NATIONAL QUALITY FORUM

+ + + + +

RENAL MEASURES STANDING COMMITTEE

+ + + + +

TUESDAY
JUNE 28, 2016

+ + + + +

The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., Constance Anderson and Peter Crooks, Co-Chairs, presiding.

PRESENT:
CONSTANCE ANDERSON, BSN, MBA, Co-Chair; Vice President of Clinical Operations, Northwest Kidney Centers
PETER CROOKS, MD, Co-Chair; Senior Consultant - Renal Business Group, Kaiser Permanente
ISHIR BHAN, MD, MPH, Director of Nephrology Informatics, Partners Healthcare, Massachusetts General Hospital
LORIEN DALRYMPLE, DNP, Nurse Practitioner, American Nurses Association
ELIZABETH EVANS, DNP, Nurse Practitioner, American Nurses Association
MICHAEL FISCHER, MD, MSPH, Staff Physician, Associate Professor of Medicine, Department of Veterans Affairs
STUART GREENSTEIN, MD, Professor of Surgery, Montefiore Medical Center
DEBRA HAIN, PhD, APRN, ANP-BC, GNP-BC, FAANP, Associate Professor, Adult Nurse Practitioner, Doctor of Philosophy, Doctor of Nursing Science, American Nephrology Nurses' Association

LORI HARTWELL, President/Founder, Renal Support Network*
FREDERICK KASKEL, MD, PhD, Chief of Pediatric Nephrology, Vice Chair of Pediatrics, Children's Hospital at Montefiore Medical Center
MYRA KLEINPETER, MD, MPH, Associate Professor of Clinical Medicine, Tulane University School of Medicine
ALAN KLIGER, MD, Clinical Professor of Medicine, Yale University School of Medicine; Senior Vice President of Medical Affairs, Chief Quality Officer, Yale New Haven Health System
LISA LATTS, MD, MSPH, MBA, FACP, Deputy Chief Health Officer, Watson Health, International Business Machines Corporation
KARILYNNE LENNING, MHA, LBSW, Senior Quality Improvement Facilitator, Telligen
FRANKLIN MADDUX, MD, FACP, Executive Vice President for Clinical and Scientific Affairs, Chief Medical Officer, Fresenius Medical Care North America
ANDREW NARVA, MD, FACP, FASN, Director, National Kidney Disease Education Program, National Institute of Diabetes and Digestive Kidney Diseases - National Institute of Health
JESSIE PAVLINAC, MS, RD, CSR, LD, Director, Clinical Nutrition, Food & Nutrition Services, Oregon Health & Science University
MICHAEL SOMERS, MD, Associate Professor in Pediatrics/Director, Renal Dialysis Unit; Associate Chief, Division of Nephrology, American Society of Pediatric Nephrology/ Harvard Medical School/Boston Children's Hospital
JOHN WAGNER, MD, MBA, Director of Service, Associate Medical Director, Kings County Hospital Center
JOSHUA ZARITSKY, MD, PhD, Chief of Pediatric Nephrology, Nemours/A.I. duPont Hospital for Children

NQF STAFF:
ANN HAMMERSMITH, JD, General Counsel
POONAM BAL, Project Manager
ANDREW LYZENGA, Senior Director
YETUNDE ALEXANDRA OGUNGBEMI, Project Analyst
SARAH SAMPSEL, Senior Director
KATHRYN STREETER, Senior Project Manager

ALSO PRESENT:
JOEL ANDRESS, PhD, Centers for Medicare and Medicaid Services
JENNIFER BRAGG-GRESHAM, PhD, University of Michigan School of Public Health*
CLAUDIA DAHLERUS, PhD, University of Michigan Kidney Epidemiology and Cost Center
RONALD HAYS, PhD, Fielding School of Public Health, University of California, Los Angeles*
SEHEE KIM, PhD, University of Michigan Kidney Epidemiology and Cost Center
JOE MESSANA, MD, University of Michigan Hospitals and Health Centers
LISA McGONIGAL, MD, MPH, Kidney Care Quality Alliance*
ROBYN NISHIMI, PhD, Kidney Care Quality Alliance*
DOUG SCHAUBEL, PhD, University of Michigan Kidney Epidemiology and Cost Center
JON SEGAL, MD, University of Michigan Kidney Epidemiology and Cost Center
JACK WHEELER, PhD, University of Michigan Kidney Epidemiology and Cost Center
ELIZABETH WITTEN, Witten and Associates

*** Present by teleconference**

A-G-E-N-D-A

P-R-O-C-E-E-D-I-N-G-S

9:04 a.m.

MS. STREETER: Hello. Good morning, everyone. I think we'll go ahead and get started. I'm Katie Streeter, senior project manager here with the Renal Team at NQF and we just wanted to go over a few logistics before we proceed with the meeting.

As a reminder, this call, as all of our calls, is open to the public. So please remember to mute your line if you're on the phone. It just really helps with the noise.

All of our materials are available on the committee SharePoint page. If you're having any difficulty accessing the documents please email Poonam or myself, and we can help you with resetting your password or whatever else may be needed.

Also, just as a reminder, if you wish to speak at any time during your meeting, you can put your name tag up like this, and we will be sure to call on you.

Also, the speakers all have an on and off button. Only three microphones can be on at one time. So if you're not speaking please be sure that the microphone is off.

I would like to turn this over to Ann Hammersmith, our general counsel, so she can begin with roll call and discussing disclosures of interest.

MS. HAMMERSMITH: Thanks, Katie. I'm Ann Hammersmith. I'm NQF's general counsel. Those of you who have served on this committee or another committee at NQF are familiar with the oral disclosures. I'll go over the instructions quickly, and then we'll go around the table.

You received a rather lengthy form from us when you applied to sit on the committee. We asked you detailed questions about your professional activities.

Now we are going to ask you to go around the table and disclose what you believe is relevant to your service on the committee, only if relevant to the service on the committee.

So we're particularly interested in your disclosure of relevant consulting, speaking, research grants. Don't have to disclose every grant you've ever gotten, only if it's relevant to the subject matter before the committee.

Just because you disclose does not mean you have a conflict. You may have served on a committee for a professional society or something like that. That is not necessarily a conflict.

So with that, let's go around the table. Tell us who you are, who you're with and if you have anything to disclose. We'll start with the co-chairs.

CO-CHAIR CROOKS: Let's try that one. Good morning, everyone. I'm Peter Crooks, and it's my fourth time, I think, I've had the pleasure to co-chair this meeting, and I'll just say welcome to everybody, and thank you for coming.

I would disclose that I was a quality developer as -- a developer for the measure last

year. I'm getting into the time zone here. Excuse me for a second as I move from West Coast to East Coast time.

I was a developer on the optimal ESRD starts measure that was approved last time, which is conceivably related to the vascular access measures that are on the docket today.

In talking it over with the staff and thinking it through, I don't think it's truly related. It's a different population.

But if anybody on the committee has concerns about, it you can speak now or soon, and I can recuse myself from those measures discussions if needed. Otherwise, I can think of no other disclosures. Connie?

CO-CHAIR ANDERSON: Good morning. I'm Connie Anderson from the Northwest Kidney Centers in Seattle. I was a member of the NCQA or NRAA Quality Committee. But there is no conflict of interest there.

I was part of the KCC Quality Group, KCP Quality Group but it's been two years. So I

have nothing to disclose.

MEMBER KASKEL: I'm Rick Kaskel, a pediatric nephrologist from Albert Einstein College of Medicine at Montefiore Medical Center. I think it's the third time I'm sitting on the committee. I don't have any conflicts of interest, and I work with ASPN, American Society of Pediatric Nephrology.

MEMBER GREENSTEIN: I'm Stu Greenstein, a transplant surgeon at Montefiore Medical Center. I guess I'm the only surgeon here so I'll try to be quiet most of the times.

And I have no conflicts. I also represent the American Society of Transplant Surgeons.

MEMBER MADDUX: Hi, I'm Frank Maddux. I am chief medical officer and nephrologist of Fresenius Medical Care North America. I am also the chair of Kidney Care Partners, which is a sponsor for the Kidney Care Quality Alliance.

I have not been involved in the measure development that we're going to have

under discussion at 3:30 p.m. on medication reconciliation.

But I have had prior extensive discussions with CMS and others from a technical expert standpoint on the Measures 2977 and 2978 related to vascular access in catheters. Those would be my disclosures.

MEMBER SOMERS: I'm Michael Somers. I'm a pediatric nephrologist from Boston Children's Hospital. I don't have any disclosures.

MEMBER DALRYMPLE: My name is Lorien Dalrymple. I'm a nephrologist at U.C. Davis. With respect to the measures today, I did serve on the CMS Technical Expert Panel for Comorbidity Adjustment for the SHR and SMR.

I did participate in the face validity testing of the medication reconciliation measure that we'll be discussing later today. I do receive research support from a number of organizations.

But they include Dialysis Clinic

Incorporated, which is a dialysis organization and AHRQ for quality indicators. But those are related to PSIs and IQIs.

I don't know if we will be discussing the metrics submitted by Peter last year, but my husband is a physician partner at Kaiser and has shares in TPMG.

And last, I'm currently employed by U.C. Davis but effective September of this year will be with Fresenius.

MEMBER BAHN: I'm Ishir Bhan. I'm a adult nephrologist at Mass General Hospital, and I have no disclosures.

MEMBER FISCHER: I'm Michael Fischer. I'm an adult nephrologist at the Jesse Brown and Hines VA in Chicago. I am a member of the VA Dialysis Steering Committee where we work on developing our own internal performance measures.

I'm also a member of the RPA Quality Safety and Accountability Committee.

MEMBER LENNING: Good morning. I'm Karilynne Lenning, and I work for a company

called Telligen, currently contracted with the state of Iowa to work on the state innovation model, and I have no disclosures.

MEMBER NARVA: I'm Andy Narva. I'm a nephrologist at NIDDK. I direct the National Kidney Disease Education Program, and I have no conflicts. Only existential ones.

MEMBER WAGNER: Good morning. I'm John Wagner. I'm a nephrologist in Brooklyn, New York. I am the associate medical director of New York City Health and Hospitals, Kings County, and the President of the National Forum of ESRD Networks.

I'm a director emeritus of IPRO, which is a quality improvement network, and my forum has a membership on the KCQA, although I haven't participated directly in those activities, and I've served on a prior TEP panel that had to do with quality metrics in ESCOS. But I don't believe I have any conflicts for today.

MEMBER HAIN: Hi, I'm Debbie Hain. I'm an associate professor at College of Nursing

at Florida Atlantic University in Boca Raton and I am also a nurse practitioner in the Department of Nephrology at Cleveland Clinic, Florida. I don't have any disclosures related to the measures today.

MEMBER EVANS: I'm Beth Evans. I'm a nephrology nurse practitioner in Albuquerque, New Mexico working with a private practice. I'm representing the American Nephrology Nurses Association, and I have no disclosures.

MEMBER PAVLINAC: Good morning. Jessie Pavlinac, Director of Clinical Nutrition at Oregon Health and Science University in Portland and a transplant dietician.

I serve on the Network 16 Board of Directors and the Medical Review Board is the only thing I can think of. We're interested in quality indicators, of course.

MEMBER KLEINPETER: Hi, I'm Myra Kleinpeter, adult nephrologist, Tulane University. I've served on the previous version of this committee, also on the committee looking

at ESCOs, and on the Medical Review Board for Network 13, and I have no conflicts of interest at this time.

MEMBER LATTS: Hi. I'm Lisa Latts. I'm an internist. As of last week, I'm the Deputy Chief Health Officer with IBM Watson Health, and I have no conflicts.

MEMBER KLIGER: Hi. Alan Kliger. I'm a nephrologist in New Haven, Connecticut, employed by the Yale New Haven Health system as their chief quality officer, and I was nominated to this committee by the Renal Physicians Associations, and I have no disclosures.

MS. HAMMERSMITH: Okay. I believe we have a committee member on the phone, Lori Hartwell. Is Lori Hartwell on the phone?

MEMBER HARTWELL: Yes. Good morning, everyone. My name is Lori Hartwell, and I'm the president and founder of Renal Support Network, and I've been a patient since 1968.

I'm a board member of Kidney Care Partners, but I have no disclosures.

MS. HAMMERSMITH: Okay. Thank you. Is there anyone else on the phone, any other committee members?

Okay. Just a few reminders before I leave you today. You are all experts, and that's why you're serving on the committee. You don't represent your employer. You don't represent anyone who's nominated you for service. You don't represent a professional society to which you belong. You are subject matter experts, and you sit as individuals.

The other reminder is that to make a conflict of interest process work we count on all of you as committee members. So if during the meeting you think that you have a conflict, if you think somebody else has a conflict, or you think that someone is behaving in an unduly biased manner, we ask you to speak up in real time. You're always welcome to bring it up in the meeting.

If you'd rather not do that you can go to your co-chairs who will go to NQF staff, or

you can go directly to NQF staff. Any questions or comments? Questions for each other or questions for me?

Okay. Thank you.

MS. STREETER: Thank you. At this time, I'd also like to have the opportunity for my team members to introduce themselves. Poonam?

MS. BAL: So I'm Poonam Bal, the project manager on this project. I look forward to working with you guys again.

MR. LYZENGA: Hi, Andrew Lyzenga, senior director on the project, my first time working with this topic area and with this committee. So look forward to working with you all as well.

MS. SAMPSEL: I'm Sarah Sampsel, basically considered, I guess, a consulting senior director. Since I worked with you all last time, I'm now full time with NQF, and so I'm just supporting Andrew in the transition as he takes over this work.

MS. OGUNGBEMI: Good morning. I'm

Alexandra Ogungbemi, and I'm the project analyst on the Renal Standing Committee.

MS. STREETER: I'd also like to point out that we have Elisa Munthali and Marcia Wilson here with us from NQF. Oh, we have -- Mike's coming. Oh.

But thank you for being here with us today as well, and thank you all for being here with us today. This is our second in-person meeting as a standing committee.

Just a refresher, some ground rules for today's meeting. During the discussions all committee members, co-chairs, developers and staff are responsible for ensuring that the work of the meeting is completed during the time allotted.

During these discussions, committee members should be prepared, having reviewed the measures beforehand. We did receive your comments through the worksheets on SharePoint, and we have incorporated them into each measure worksheet.

We ask that you base evaluation and recommendations on the measure evaluation criteria and guidance. Please remain engaged in the discussion without distractions. Keep comments concise and focused. Avoid dominating a discussion and allow others to contribute, and indicate agreement without repeating what has already been said.

Process for measure discussions, we are very fortunate to have the measure developers present at our meeting. We do have a place designated at our main table for the introduction and discussion of their measures so that they may more easily respond to questions from our committee and correct any misunderstandings about their measures during our discussion.

As with the case with the committee members, developers may put up their cards to indicate when they wish to respond to questions raised or correct any statements about their measures.

So voting on endorsement criteria,

just a quick refresher. We do have four main criteria that we will be using as a basis to evaluate the measures. The criteria are specific in the -- the criteria are in the specific order in that there is a hierarchy. The first two are must-pass criteria: importance to measure and report, and scientific acceptability of the measure properties. We then move on to feasibility and usability and use.

We do have a new maintenance process that has been implemented since we last met, and when we get to our first maintenance measure for review we will walk you through that new process.

So voting during today's meeting, you should all have a clicker. If you do not, please let us know. As like last time, you will aim your clicker towards Yutende here and -- are we doing a test or no? We can do a test just to make sure everyone's clicker is working. We do have one remote participant, Lori, and she will be voting through our online web platform.

So related and competing measures, we

have identified some related and competing measures. The way we structured our agenda is that after we review each measure, if there happens to be relating and competing measures, we will have that discussion afterwards.

Developers were asked to consider how they can work together or otherwise align measures, and the committee will be invited to ask developers about harmonization opportunities when each measure is being discussed.

And if we -- are there any questions about the process for today's meeting? And if not, we can jump right in to our first measure. Actually, we'll start with our test, yes, test for voting.

MS. BAL: So we're just going to do a quick test to make sure that everybody's clicker is working. As you remember, if you see the number that means it went through. If you do not see the number, there's an error, and it did not go through. Give us one second to get it up.

You can change your decision as long

as the screen is up. Also try not to change it at the end once we've started the announcement.

Okay. So we have it up. All right. So if everyone could just select something, and then Lori, on the phone, if you could just reply to my chat with any number just so we can make sure we're getting it. All right. So I'm seeing 17.

If everyone can just click it again, and please look at your screen to make sure the number is showing up. And Lori, I did get your messages.

MEMBER HARTWELL: Thank you. I'm going to put you on mute, so I might take a minute to answer, or a second.

MS. BAL: We're missing one person. I'm just going to recount the people to make sure that I'm on the right number. Hold on a second.

Okay. So it's slow. But I think everyone's clicker is working, and we can move forward with our first measure then, and I'll give it to the co-chairs. Oh, I'm sorry.

Andrew.

MR. LYZENGA: I think we had one -- just we had one slide to just run -- quickly run over the portfolio. I won't spend much time on that either, just to remind you of some of the general topic areas we're looking at here and that we have in the portfolio.

I think most of this group is probably pretty familiar with the measures in the portfolio at this point. A few measures around dialysis monitoring, monitoring for various markers to try to avoid complications and identify them, some measures related to dosing and dosing adequacy, a bit of -- some measures related to hemodialysis, vascular access. We'll have some discussion around that, and then some general measures related to ESRD management.

There is a sheet in your materials that were printed out for you at your desk where you can look through the full set of measures in the portfolio, and I would encourage you to take a look at that maybe during one of our breaks or

just during the day. So we will try to have a brief conversation at the end of the day.

If we have some time around gaps, if you have suggestions or ideas on gap areas in this portfolio, areas where you think there needs to be some more measure develop on the renal topic area, we would welcome your input on that.

But I think we can kind of skip over this and just get into the meat of our meeting in the interest of time at this point and go to our first measure, which I think is going to be our measure related to the KDQOL survey.

Beth, did you want to comment?

CO-CHAIR CROOKS: We just came to 45 minutes. That's --

CO-CHAIR ANDERSON: We're way ahead of schedule.

MS. WITTEN: Press speak. What a unique way.

My name is Beth Witten. I'll just try to -- I'm going to be reading my intro. Because this is such an important measure, I want to make

sure that I say what needs to get said.

The current conditions -- well, first of all, the measure is 0260, and it's an assessment of health-related quality of life in eligible patients, to be assessed once a year, and that's not the exact wording of it.

But the current conditions for coverage require clinics to offer eligible patients a functional status survey at least annually. This is an absolutely essential measure because it is the only one that asks patients how they feel about their lives on dialysis physically, mentally, symptoms, burdens and effects of kidney disease on their daily life.

The current NQF-endorsed process measure collects the percent of eligible patients who complete the KDQOL-36, the 36-item survey, with our without help at least once a year.

The scope of this review is whether this process measure, not the survey, is reliable, valid, feasible and usable. We kept

the exclusion for language.

The ESRD interpretive guidance recommends using a translation or interpreter like the language line, and, by the way, the RAND site has 25 translations on it that can be used to translate either the survey itself of 36, or there's a chart that allows you to choose which questions to ask.

If clinics exclude patients who speak or read certain languages how will they provide the mandated education and informed consent? Are there differences in language exclusions or patients' completions based on social work caseload? We don't know that. That's something that would be interesting to investigate.

We did change some other exclusions to address misunderstanding and conform to the CFC. We changed "less than three months at the facility" to "less than three months on dialysis" so the facility could consider baseline survey results in the first reassessment in plan of care required by the CFC during the fourth month of

dialysis.

We expanded the exclusion for cognitive impairment, dementia or psychosis to "unable to complete due to mental status" but would be willing to revise this to "unable to complete due to mental status that would invalidate the results".

This would avoid staff excluding patients with depression, anxiety or other mental health diagnoses that would not invalidate the results.

We removed "refused" from the exclusion criteria so these patients will not be removed from the measure denominator. We wanted to allow patients the right to refuse, which is their right, while also assuring that facilities track individual patient refusals for plan of care and aggregate date for quality assessment and performance improvement.

Removing refusals as ineligible from the denominator would result in a completion rate at or near 100 percent. Response rates from one

large dialysis organization and KDQOL Complete, which is the subscription service, were greater than 80 percent and improving somewhat.

Different completion rates may reflect how relevance and use of the survey are described to patients. Please note that the scope of this process measure was not to show whether the KDQOL-36 is reliable or valid. This has been documented in the U.S. and other countries, ethnicities and languages.

The scope was not to assess whether the scores are meaningful to outcomes, though we did discuss this on Page 37 and that's at 2b.2.3.

And the scope was not to assess whether interventions can change scores, although multiple randomized control trials and posters at national meetings have shown that they can.

We are seeking continued endorsement of the current measure of percent of eligible patients completing the survey with the goal of bringing to NQF within a year an outcome measure.

And assuming that they're on the

phone, because they didn't expect to get on the phone until a little bit later, I'll let Jennifer Bragg-Gresham answer questions about her analysis of the data, and Ron Hays answer questions related to the reliability and validity of the KDQOL-36 survey itself, because he was one of the developers.

MR. LYZENGA: Just a quick note. As we mentioned on our Q and A call, under our new maintenance process, we have the ability to skip over certain sections of evidence and scientific acceptability if the committee feels that's appropriate.

I think we, at the staff level, are thinking that this measure has changed fairly substantially. It's gotten new testing, new evidence as a process measure since its last review. So our recommendation is that we review each of the criteria on this measure instead of skipping over them if the committee thinks that's appropriate.

CO-CHAIR CROOKS: So we're going to --

so when the other speakers come on, are we going to stop and let them --

MS. WITTEN: Well, that was one of the questions I probably should have asked you guys. Because I don't know how you run your meeting. I didn't know whether you had discussion based on your comments that were made, or whether our folks needed to discuss --

CO-CHAIR CROOKS: Were they going to present different material or were they --

MS. WITTEN: They were going to -- no, they were going to answer questions.

CO-CHAIR CROOKS: Yes. So maybe by the time they come on we'll be able to ask them any needed questions.

DR. HAYS: Yes. I'm on. Ron Hays. But you probably want Jennifer more than me for this. But I'm available for questions.

MR. LYZENGA: I think at this point we can hand it over to our lead discussants and just have those folks available on the phone to answer questions or make clarifications if necessary.

MS. WITTEN: And I think Lorien is going to go ahead and take the lead on this, and Bobby isn't here today, so Lori Hartwell and I will add in our comments as Lorien presents the information.

MEMBER DALRYMPLE: Okay. So we'll go ahead and get started. As already mentioned, this is NQF Measure Number 0260, Assessment of Health-Related Quality of Life in Dialysis Patients.

Just briefly to remind everyone, the numerator statement is the number of eligible individuals with end-stage renal disease on any type of dialysis who complete a KDQOL-36 with our without assistance once per calendar year.

The denominator statement is the number of individuals with ESRD, again, on PD in-center hemo or home hemo, treated by the dialysis facility during the calendar year, minus those patients who meet exclusion criteria.

The exclusion criteria have been significantly revised since prior endorsement and

now include those who are less than 18 years old, those who are unable to complete the survey due to mental status that could invalidate the results, those who are non-English speaking or reading and no native language translation or interpreter is available.

Those who have been on dialysis for less than three months, and then it's noted those who decline to complete one survey can then be subsequently surveyed and counted during the calendar year.

So I will attempt to follow the script and first, we just note that this is technically undergoing maintenance review, but as pointed out, it's been significantly revised with a lot of new data.

So we will walk through it as if it is a new measure. It was most recently endorsed in 2007. This is a process measure. In terms of the evidence presented, it primarily relates to the KDOQI Clinical Practice Guideline, looking at associational level of GFR with indices of

functioning and well-being, and in this guideline, it is suggested to establish a baseline and monitor for changes in functioning and well-being over time and that this is important to assess the effect of interventions on functioning and well-being.

Connie, would you like to add anything else, or Lori, who's on the phone, to the basic premise of the evidence before we go into details of rating?

MEMBER HARTWELL: I think you covered it.

CO-CHAIR ANDERSON: I think my only comment is -- sorry. My only comment is in terms of the GFR less than 60, and I'm wondering, since this is focused on PD home hemo and in-center patients on dialysis, I question the GFR of less than 60 just because that's -- you're looking at then chronic kidney disease patients at stage 2, 3, 4. So I wonder if that's --

MS. WITTEN: Well, our measure just addresses patients that are on dialysis. So

although the KDOQI said less than 60, people that are on dialysis have a GFR of less than 60. But we are just asking for this related to eligible dialysis patients.

MEMBER DALRYMPLE: And one aspect that at least I thought it would be helpful for the committee to discuss at large is it always becomes a little bit difficult, I think, when the evidence relates to something that's not directly the measure under discussion.

So the measure under discussion is, did you complete the KDQOL? It is not a measure of functioning or well-being or what your PCS or MCS scores are.

So personally, when I try and go through algorithm one and try and rate the evidence, it depends on how you interpret the evidence relative to the measure.

So I'm curious whether other committee members -- for example, if you go down our boxes, does this fall more as a distal process step, for example? Because you rate the evidence very

differently if you argue this as a distal process step: completeness yes/no of the KDQOL-36 on an annual basis.

So I thought it would be helpful for us to discuss that as a group before we try and rate the evidence relative to algorithm one.

So yes, and this is where I'm always grateful for the staff because they're going to hopefully stop us if we're going through the boxes first.

So if we start at box one, this is technically a process of care. Although I recognize that the HRQOL is a patient-reported outcome, that's not how this measure is specified. This is measured as a process: did you complete it, yes or no?

So my answer to box one is no. So then you have this kind of wordy question that look at measures that assess performance on an intermediate clinical outcome, process, or structure. Is it based on a systematic review? But down below there's these little caveats.

Answer no if any of the following: evidence is about something other than what is measured; empirical evidence submitted but not systematically reviewed based on expert opinion.

But you get down to this last asterisk: distal process step is not the specific focus of the evidence, such as monitoring BP at each visit when the evidence is about treatment of hypertension or relationship to mortality.

So my perspective was that this measure is more a distal process step. It's completion yes/no of a survey, not what are the results of your survey.

So I answered no on this box. So then I went down to number seven, is empirical evidence submitted but without systematic review? And the answer to that is no because we did get systematic review in grading of the evidence, although it's a slightly different grading schema than the ones we're used to.

It has a lot of Rs, and there was one S and one C. So then we get to ten, are there or

could there be performance measures of related health outcome or evidence-based intermediate clinical outcome or process?

I would answer that yes because technically speaking the results of the KDQOL could be an outcome, I believe. So then no exception, no exception, no exception, and I got to rate as insufficient.

But I know on the NQF staff's preliminary eval, I think they got to a rating of moderate. So I thought this was an area worth us parsing out as a committee because when I worked through the algorithm I rated it as insufficient.

MS. WITTEN: By the way, right now I've got both Ron Hays -- well, actually I've got three people on the phone: Ron Hays; Jennifer Bragg-Gresham, who ran the statistics for us; and Kristi Klicko, who handles the KDQOL Complete, knows about the subscription service that scores, reports, analyzes the data for that particular program.

MEMBER ZARITSKY: I'll start off by

arguing with number ten. I mean, I understand -- I could answer number ten as no because I think the meaningful thing is here there -- if I look at the example for yes, propose to measure whether BP is assessed at each visit instead of BP control, I mean, here there -- I could answer that no and then make it over to rate as insufficient evidence with exception.

MEMBER DALRYMPLE: And I believe we always have the ability to do exception on evidence, right? Regardless of which box we end up on, the committee can make an exception, and we move forward in evaluating the measure? Is that correct?

MR. LYZENGA: Yes, and we would first take a vote, and if it came out as insufficient, then we could revisit the question and ask, do we want to make an exception? And rate it insufficient with exception, and then we would move on to the subsequent criteria.

MS. SAMPSEL: And I would just add, Lorien, this isn't a new struggle. I mean, we

deal with process measures, and typically where we're seeing them are, was functional status assessed for orthopedic issues? Or something like that. We also see it with pain measures. Just simply, did you assess for pain? And certainly there was a lot of support that that's very important. It's supported in guidelines, et cetera, and that is -- just if you care about consistency's sake that is -- they're going through with the exception of evidence.

MS. WITTEN: I'm having a little bit of question about the process measure and why you believe that it's not a process measure. I'm not -- I've not researched it that closely.

MEMBER DALRYMPLE: We did -- oh, just to clarify, we do believe it's a process measure.

MS. WITTEN: Okay.

MEMBER DALRYMPLE: We're just following the algorithm for evaluating evidence as it relates to a process measure.

MS. WITTEN: Okay.

MEMBER DALRYMPLE: So everyone's in

agreement with what you submitted. This is a process measure.

MS. WITTEN: Okay. Okay.

CO-CHAIR ANDERSON: Okay. Is there any further discussion? Are we ready to vote?

Oh, I'm sorry. Alan?

MEMBER KLIGER: I just had an issue unrelated to what you raised. In the definition of denominator exclusions is included "mental status that could invalidate the results", and I can't imagine how you would define a mental status that would specifically invalidate the results.

MEMBER DALRYMPLE: And Alan, I think there's actually a lot of the exclusions that need to be discussed probably in more detail. And whether we want to do that at the validity phase or sooner, but there are a number of denominator exclusions that I think the committee is going to raise concerns about.

CO-CHAIR CROOKS: I'd like to ask the developer, this is about importance, a little bit

off the evidence. But is this not a CMS condition of coverage that this be measured already?

MS. WITTEN: This is.

CO-CHAIR CROOKS: And if that's the case, what does having a measure add to the mix?

MS. WITTEN: We just wanted to maintain the measure. It was introduced -- the history of this particular measure is that it was introduced by Donna Mapes, who was part of DOPPS.

She and I worked on this in 2006-2007, and NQF endorsed it in 2007. The regulations were in process of being reviewed and revised in all of that time, and NQF endorsed it. CMS adopted it under the Phase III clinical performance measures on April the 1st of 2008.

But it was too late at that point to get that into the regulation that this particular survey be used. So it is in the conditions for coverage that a social worker is supposed to assess the health-related quality of life at least once annually, and so the DOPPS data just

recently that was published shows that 97 percent of their sample facilities in the United States are surveying patients once a year for this particular measure, and there are 13 percent of facilities that are assessing patients at least every six months.

So it's in use, and I'm not sure if that quite answers your question or not. But we're just trying to maintain the endorsement in the plan for using the data that we now have, which we didn't have in 2007, to come up with an outcome measure because I think that would be more valuable than this particular measure.

But this particular measure, as you said, Sarah, is very similar to assessing pain or assessing depression. It's, did you assess it/did you not assess it? I would love to see this in the CROWNWeb data.

We've been talking with CMS CROWNWeb people about that, trying to get this in there to look at is it assessed or is it not.

It looks like from DOPPS that it is

being assessed, and I know from data from Fresenius and DaVita and from DCI and various dialysis providers this process measure, it is being done.

So percent of eligible patients taking the survey, I learned from Fresenius that about 85 percent of their patients are completing the survey, and approximately that amount, 80, over 80 percent in the KDQOL Complete database are completing it.

CO-CHAIR CROOKS: Okay. Thank you. So we need --

MEMBER DALRYMPLE: This is Lori Hartwell. I just have a comment. I am a strong proponent of the KDQOL. My one question is is that if they check the box if they did the survey or not, I'm reading through the SF-36, and in my opinion many of the questions don't really apply to how dialysis units can really improve my care, and so I think -- for instance if you go through the KDQOL, like, one of the questions is have you felt calm and peaceful?

And one of my struggles is, as a patient, the clinic needs to ensure that my treatment is the best possible so I don't -- I can go out and improve my quality of life.

So the question that -- there are several of them, but, do you have cramps, do you have itchy skin, these all impact my quality of life, but the dialysis unit can actually impact.

They can educate me about phosphorous, fluid retention. My one thought is if it's just a process measure, that's fine. But if there were ever to be an outcome measure, I think the questions need to be shrunk so the dialysis unit can actually improve it because some quality of life is up to the patient to improve, and we need to take a little responsibility.

But if we do not have a good treatment, and we do not feel good, we cannot make a difference in our own quality of life.

MS. WITTEN: Can I address that?

CO-CHAIR CROOKS: Briefly. This is --

MS. WITTEN: Going on longer.

CO-CHAIR CROOKS: I guess her comment relates to, again, the importance of it. If it's not the right instrument, or it's not measuring the right thing, why should we be endorsing it, I guess.

MS. WITTEN: The KDQOL-36, separate from the SF-36, the KDQOL-36 has the first 12 questions are from the SF-36, but then they have specific kidney-related questions, which -- the SF-36 is what's called a generic instrument, and this is a disease-specific instrument.

So this gets at the burden of kidney disease, the symptoms and problems that a lot of kidney patients have, people that are on dialysis, and also gets at the effects of kidney disease on their daily life.

And I can tell you that I've gone through this survey, and I have come up with -- and this is not part of the measure -- I have come up with things that various members of the interdisciplinary team could do to address each of the questions. And Lori is right. It's

important to address the results.

CO-CHAIR ANDERSON: I have a question for the developer as well. Back in 2007-8 when the conditions for coverage came out, things have changed dramatically over those years, and now we have pain assessments twice a year.

We have ICAHPS twice a year. We have depression screening twice a year, and now KDQOL at 120 days and then annually or more frequently. And I'm concerned, and maybe it's a better discussion for performance gap, of the burden of surveys on our patients at this point.

And in 2016, as we're halfway through the year, we're seeing a real decline in response rates, and so I'm just real concerned about the burden of survey, and Lori, I don't know if you want to make a comment on that but -- and maybe we should hold it for performance gaps.

But we are measuring our patients so frequently with so many things that are now mandated that from a provider standpoint and from a patient perspective, we're hearing it's an

overburden.

MEMBER HARTWELL: I'm all for measuring as long as somebody is reacting to what I remark. I mean, if I fill out a survey, I expect the unit or whoever is conducting the survey to address what I just said. And so that's the one -- the only thing that I would stress is where patients, I believe patients get fatigued. They fill out the survey. Nothing changes.

MS. WITTEN: And I agree that patients do have a lot of surveys to fill out. This particular survey, though, is a broader survey than just assessing for depression, and I'm thrilled that they're assessing for pain.

I wish it was more than twice a year. I personally would like to see it, how's your pain, at each treatment. But I understand that filling out a survey, that would be difficult.

I do think that people need to do the survey, get the scores and go back to the patient as soon as possible with those scores and talk to

them about what could be done about it.

CO-CHAIR CROOKS: So in one sense, it may not -- in terms of evaluating, it may not matter actually what's on the survey. The case that I think they're trying to make is the process of doing the survey causes -- is linked to good outcomes.

Is that what the committee understands? In other words, if that was the case, it may not matter per se what's on the survey from the logic of -- no?

MEMBER DALRYMPLE: I'm not sure I understand the question, Peter. I mean, I would suggest we move forward with voting on evidence because I feel like we're getting to other domains of evaluation, and if we need to discuss the evidence more in length, but the measure as specified is whether you did or did not complete the KDQOL, and so it is a process of care. It is, I think, a reasonable assumption that for you to intervene on someone's functioning and well-being, you have to complete a survey which

measures that, and the very first step in that process is, yes or no, did you attempt to administer and complete it?

But I think we should vote on the evidence as it relates to the measure and then move to the other domains because I feel like the discussion is getting to other areas where I think there will be a lot of robust discussion.

CO-CHAIR CROOKS: Before we vote on evidence. Okay. Then let's take --

MS. BAL: All right. So before we start, I just wanted to make one clarification. If you are in favor of doing insufficient with exception, we do have to get 60 percent or more insufficient.

So if we don't get over 60 percent, and then let's say more than 40 percent low, that does not move forward for insufficient.

We would not vote on insufficient with exception then. Is that clear for everyone? Okay. I just wanted to make sure. Okay. So I'll give it to Alexandra to start the vote then.

MS. OGUNGBEMI: All right. We are now voting on Measure 0260, Assessment of Health-Related Quality of Life in Dialysis Patients. We are voting on evidence. Voting is open.

MS. BAL: Lori, please enter your vote through the chat.

MS. BAL: We are still missing -- never mind.

MS. OGUNGBEMI: Voting is closed. Our results are 0 percent high, 26 percent moderate, 16 percent low, and 58 percent insufficient.

MS. BAL: So we actually do need to do a revote though because we have 20 people with Lori on the phone, not 19. So we'll have to do another vote because that one vote could make a big difference.

MS. OGUNGBEMI: All right. We are now voting on evidence for Measure 0260. Please vote.

MR. LYZENGA: So in that case, I think we will take a second vote to --

MS. OGUNGBEMI: So our results are 0

percent high, 25 percent moderate, 15 percent low and 60 percent insufficient. So we are going to move on to vote for evidence with exception.

We are now voting on Measure 0260, evidence with potential exception to empirical evidence. The options are one, insufficient evidence with exception, and number two is no exception. Please vote.

MS. BAL: Lori, we are waiting for your vote. Could you please send through the chat? We received it. Thank you.

MS. OGUNGBEMI: The results are 70 percent insufficient evidence with exception and 30 percent no exception. So Measure 0260 passes with insufficient evidence with exception.

MEMBER DALRYMPLE: Okay. So we will move on with opportunity for improvement. On page 19 of the measure initially forwarded to the group, there is information provided by the developer on differences in the performance measure between facilities that participate in KDQOL complete and have at least 10 patients.

I think we can just -- although we have data from 2013, 2014 and 2015, these are overall relatively similar looking to me. So we can just discuss the 2015 data.

There were 1,261 facilities with a median score of 91.8 percent. The interquartile range was 78 to 100 percent. The tenth percentile was 61.2 percent.

So I think you could argue there is some opportunity for improvement, although I believe the developer said something that was quite interesting earlier in the presentation that this is if you include those who refuse in the denominator, and I believe she said that if you do not it's closer to 100 percent.

I may have misunderstood. But I think that will be important for us to think about as we get to the specifications. But the measure as specified, I would say, does have some room for improvement if you look at the lower probably 10 percent facilities and maybe even the bottom 25 percent.

In terms of the disparities data that's presented, it's relatively limited, and you can see that it is also presented by year 2013, 2014 and 2015, and we have information on the mean age, distribution of sex and race, and whether you do or do not have diabetes, according to whether you completed the survey, you refused or you were excluded.

And I'm not sure that we need to discuss that in detail. I think everyone had an opportunity to review it, and it's relatively limited with respect to other measures we sometimes need to review disparities data on. Also --

MS. WITTEN: I don't remember whether I heard you say it also includes all the patients in the database, not just the ones that completed the survey.

MEMBER DALRYMPLE: Yes, I focused on the ones for comparison's sake.

MS. WITTEN: Okay.

MEMBER DALRYMPLE: And Connie, did you

have other comments, or Lori?

CO-CHAIR ANDERSON: No. I think you covered it well, Lorien.

MEMBER HARTWELL: I'm good. Thank you.

MEMBER DALRYMPLE: Do we want to pull to the committee's pre-evaluations to view in real time? I think that's easier than perhaps Connie, Lori or I reviewing those.

But these are the comments the committee submitted prior to our meeting today, if anyone would like to re-highlight the important points they made in writing prior to the meeting.

MS. WITTEN: And Jennifer Bragg-Gresham is on the phone right now. Do you want her to speak to anything?

CO-CHAIR ANDERSON: Anybody have any questions or comments? Shall we move forward with the vote if there's no questions or comments?

MS. WITTEN: Can I just say one thing,

that the data that relates the completion to the outcomes is that 2b.2.3.

MS. OGUNGBEMI: We are now voting on Measure 0260, performance gap. Options are high, moderate, low and insufficient. Voting is open.

Results are 0 percent high, 60 percent moderate, 40 percent low and 0 percent insufficient. Measure 0260 for performance gap lands in the gray zone.

MEMBER DALRYMPLE: So we'll move on then. Any other comments before we - we'll move on to reliability and validity. And first we'll start with the specifications in more detail. I'm on Page 22. It's probably a later page in our most recent packet. But just to review the details, we'll start with the numerator if that's helpful to every. I'll try and be brief.

It is the number of eligible and not excluded individuals with end-stage renal disease on dialysis who complete a KDQOL-36 with or without assistance at least once per calendar year.

In terms of the denominator, it is the number of individuals with ESRD on peritoneal dialysis, in-center hemodialysis or home hemo who are treated by the facility during the calendar year minus those who need exclusions.

I think the exclusions are worth discussing in a little bit more detail and we do have very specific exclusions listed by the developer including age less than 18.

Those who are unable to complete due to mental status and it states in the details from the medical record what is specifically meant by that. I do not know and I imagine it is open to significant interpretation.

The third exclusion is non-English speaking or reading and no language translation or interpreter is available - RAND translations for the KDQOL or interpreter resources. And then the last exclusion, which I think also warrants more discussion is less than three months on dialysis, which is a revised exclusion. It previously was less than three months on dialysis

at the facility.

So from my perspective when I was reviewing this measure I think one thing that would be important to talk about as a committee is what we think is appropriate in terms of putting those who refuse into the denominator.

So they used to be excluded. If you refused you were not counted in the numerator or denominator but you now go into the denominator. In terms of other aspects of the metric as specified that I think are open to interpretation is unable to complete due to mental status, the issue around no interpreter available.

We actually have some data presented by the developers on that.

And then last, this less than three months on dialysis I think was revised to align with conditions for coverage.

But from my perspective then put a patient in a facility who may be there a very short period of time. So there's no longer a requirement that you're in that facility, let's

say, for at least four weeks or some time frame that is reasonable by which you would expect a KDQOL to be completed by the staff.

So that opens up the possibility again of a denominator that's inappropriately attributing patients to that facility and how that would be handled is unclear to me.

But I think Connie and Lori, if you want to add supplemental though and then other committee members. I think there were a number of thoughts around these specifications.

MS. WITTEN: Lori, do you want to have any comments?

MEMBER HARTWELL: I just wanted to just understand the rationale of not doing the quality of life measure in the first 90 days. Is it just because there's too much change in their life and they need to adjust? That was my only question I asked of the developer.

MS. WITTEN: Yes, that was - that was the consensus when we introduced the measure initially was that the patient was in a lot of

turmoil.

Also, another reason for aligning it with the conditions for coverage is that if you did the survey, say, within the first few weeks, say, if you did it during the second month, the first plan of care for the reassessment you want it to align with that so that you get the results in time to discuss it during the plan of care and facilities have a plan of care meeting 15 days after the first reassessment, which is supposed to be done during the fourth month of dialysis.

So it was to try to get the data as close to the plan of care meeting as possible. If you're discussing data that's two months old a lot of things may have changed.

CO-CHAIR ANDERSON: So one of my comments is you're only doing the survey annually. It's a point in time. It's at the plan of care and you're capturing data that is supposed to move on to a plan of care.

But again, things change during the course of the year. So what survey tool do you

use if somebody has a catastrophic event and you want to measure symptoms, let's say.

I'm not sure that this is really capturing what it's trying to capture in terms of identifying burden of disease, mental capacity and signs and symptoms if you're only doing it once a year and -

MS. WITTEN: The regulations say that it needs to be done annually or as needed and you talk about burden of doing a survey.

But if I were doing it I would - I'm a renal social worker by background, by the way. If I were doing it, I would do the survey. I would do an intervention.

I would do a survey to see whether my intervention made a difference, because over a year period of time somebody could be deteriorating and you could be doing all kinds of things that don't get credited to you.

So we're trying to say at a minimum. We're not trying to state a maximum. So people can do it as often as they want to do it. I

believe, Ron, you're on the phone and I think in the FAQs on the RAND site it says that, you know, even monthly. But you talk about having to weigh the burden.

CO-CHAIR ANDERSON: Well, and I think the committee needs to consider the fact of the burden of all these surveys.

If somebody is depressed I would do a depression screening before I would do a KDQOL again, or if somebody's complaining of the signs and symptoms that you get on KDQOL then do you do a pain assessment because it's chronic pain.

So I think we have so many tools and so many measures here that compete with each other in some ways.

So I think it's imperative that the committee really think about what are we trying to get out with the KDQOL. And yes, it's annually or as needed, but are some other tools that are out there that are now being regulated and on the provider to perform -- are they better tools than the KDQOL or is - you know.

MS. WITTEN: Well, the KDQOL symptoms problems list is much more than just pain.

CO-CHAIR ANDERSON: Right.

MS. WITTEN: A lot of the symptoms - itching -

CO-CHAIR ANDERSON: Congestive heart failure, yeah.

MS. WITTEN: Yeah, pain - chest pain, a variety of things that are important for physicians and nurses, dieticians, even social workers to know about.

So it's important, in my mind, to not just throw out this survey and say let's just do the pain and depression because that's going to cover the -

CO-CHAIR ANDERSON: Yeah.

MS. WITTEN: - what we need to cover. My personal belief is that only just covers a small aspect of what's going on with dialysis, and there are lots of things that can be done in the way treatment is delivered, where treatment is delivered, how treatment is delivered, that

will make a difference.

DR. HAYS: Yeah. So I think that the point about burden is an important one about any measure. You know, you don't measure it just be measuring it.

You have to have a purpose and the coordination across these different approaches is critical. But I think it's probably beyond the scope of this particular assessment.

I mean, this KDQOL is assessing a lot of different things but the focus really is on the kidney disease-targeted content that's important to patients on dialysis and, you know, it touches on pain and depressive symptoms but that's not the point of the assessment.

CO-CHAIR CROOKS: Are there comments on - other comments on specification? Are there comments on specifications? Frank.

MEMBER MADDUX: Yeah. So I have one question, Beth. Did you all analyze whether or not if you move to refusals being included in the denominator has there been any assessment of

whether that would simply increase the number of mental status conclusions?

MS. WITTEN: Jen, you did the data analysis.

DR. BRAGG-GRESHAM: Right. We did not assess that and to us refusals, you know, were an important piece that we felt should be in the denominator because those are people who weren't excluded so they really should have been eligible to complete the survey. But that's something we could look at.

CO-CHAIR CROOKS: Other questions, comments?

CO-CHAIR ANDERSON: I would like to ask the developer how you're defining mental status.

MS. WITTEN: That was one of the issues - oh, okay. Go for it.

MEMBER KLIGER: Yeah, I just want to again raise questions about this exclusion which seems remarkably confusing to me.

It says mental status - I'll start

with that. We don't have a routine way of assessing and rating mental status. We, in the record, have imprecise ways of assessing that.

But then particularly mental status that could invalidate the results - we surely never record mental status in the framework of whether they can or cannot invalidate results.

In fact, the we clinicians don't know anything about what does validate or does invalidate results. So this definition seems to me to be very troublesome.

MS. WITTEN: In the past, we had dementia and cognitive impairment and active psychosis. If that is an issue with this particular part of the measure, you know, we could fall back to that. That would not be problematic.

Those all would invalidate the results because if she's got somebody that's cognitively impaired they're unlikely to even follow what you're asking, depending on the level of cognitive impairments.

And there's also tools that will measure cognitive impairment. There's many mental status exam that's not even very difficult and primary care physicians do that all the time.

MEMBER KLIGER: Only that if you're going to make that a criterion it means that that needs to be then done and registered on every patient in the dialysis unit.

MS. WITTEN: I think the social workers in the dialysis clinic who have Master's degrees in social work should be able to assess their patients' mental status to determine whether they are cognitively impaired sufficiently that it would invalidate the results.

I was concerned when we changed the measure to be more - to be broader, that some social workers who are overburdened by caseloads and so forth would say well, my patient's depressed - I'm not going to give this survey and - or my patient is anxious.

Right now, we have some situations,

and this is anecdotal, where we have social workers that call the technical expert at Medical Education Institute and say, my patient is blind - is that an exclusion.

Then we say no, you can sit down with the patient. There's no reason why you can't fill that survey out with a blind patient.

So there are - we aren't sure. We can't know for sure that there are other reasons why people are not getting this survey. I would love to study it more to find out whether patient caseloads affect the social workers offering the survey.

I would like to know whether social workers are using the tool that we have - that Dori Schatell and I wrote that's an eight-page document that explains to them how to offer the survey, how to do the - how to tell the patient it's relevant to them so that they are interested in taking it.

It's, like, doctors don't like telling patients your - you have kidney failure - you're

going to need dialysis. The social workers hate to tell patients they have low scores.

My sense on what I tell social workers is but isn't it good that you know that this is going on right now because now you can do something about it where the patient could die if they did not know they had low scores and continued to deteriorate with nothing from the - from the clinic.

MEMBER DALRYMPLE: Frank, do you have a comment?

MEMBER MADDUX: The only comment I would have is I think with the utility of the fiscal and mental component scores in a wide variety of things other than pure outcomes for an individual, predicting patients that have more needs than others, the generalization to mental status that might exclude depression, anxiety and stress-related disorders I think would be an unintended consequence that I would want to avoid in the utility of this.

And even though I'm sensitive to the

burden, I think the KDQOL has been an incredibly important tool in developing predictive analytics on identifying subpopulations of patients with special needs. And I'm a little bit concerned that that exclusion is probably two general that might lead to essentially patients not participating.

MS. WITTEN: And so would it be - since I don't know how this group operates.

CO-CHAIR CROOKS: Let me ask the staff that question that you're thinking of. If the committee is in agreement that this is a flawed specification and it needs to be addressed can we continue consideration with the caveat that they come back to us with some language that makes it much more specific?

MR. LYZENGA: I think we would have to vote on the measure as specified right now and ask the developer to come back during public comment perhaps. You know, we could maybe revote at that time.

CO-CHAIR CROOKS: So you're saying

that we should vote on it as it is and then - okay. Okay. Other comments on specifications before we go to reliability?

MEMBER WAGNER: I just had a question regarding translation services. Do we have any data to speak to how successful use of translation services is with respect to a completion of the survey?

MEMBER DALRYMPLE: Within the measure we do have what is clearly high variability between facilities than their use of interpretation services and I think you can cross some inferences based on that.

MS. WITTEN: And if you think about it, there are states that have populations of people that speak multiple different languages. There are Spanish - there are 25 - as I said earlier, 25 translations on the RAND site that are available including American Spanish, Spain Spanish.

The KDQOL complete has several languages - Tagalog, Korean - you know, a variety

of different languages. Kristi Klicko from MEI is on the phone also and could tell you more about all the translations that are available there.

One of the things that I'm concerned about, and this is where I was talking about earlier, is that there may be situations where a social worker doesn't know what language the patient speaks and doesn't know - they've called in to the technical support at the MEI site and have just said a patient is from X country and don't know what the language is.

And so there may actually be a translation available but they're so overworked because, I mean, people that work in dialysis clinics know the caseloads are high.

They may just say a language exclusion. I wish I could guarantee that ever social worker is as invested in this measure as I am.

CO-CHAIR ANDERSON: John?

MEMBER WAGNER: Yeah. I guess I was

referring more specifically to the use of a human translator to assist in the completion of the survey.

Obviously, if there is a printed translation that's helpful. But do we know whether the use of facilitated translation and coaching is important in certain populations and does that - does that have an impact on the completion of service.

MS. WITTEN: I don't think we know whether the interpretation - who interprets the survey to the patient makes a difference or not. But language line and various - there are certified interpreters that are medical interpreters that the facilities could call upon to do this.

The other thing is for large dialysis organizations if they know that they have patients that speak different languages could probably get a translation of the survey for that language.

CO-CHAIR ANDERSON: And from the

provider's side maybe I can provide you with some help and information. We use a system called On Demand.

Again, it has lots of different languages on it but, again, the variability of the translation is really high and I'll give you an example.

We translated angel food cake with one of our dieticians and it got translated to cake of death.

So you never really know what they're saying because you don't speak the languages and so we know there's variability in using interpretive services. If it's in a written language you're much better off.

MS. WITTEN: But would it be better to exclude those people and not give them -

CO-CHAIR ANDERSON: And not to say they have the same problems as the rest so -

MS. WITTEN: Yeah. The one thing that I think about is if you've got a language difficulty how are you educating patients? How

are you getting informed consent with those patients? You have to do that too.

So, you know, it seems reasonable that you could use the same people that you're using for that because you're relying on that for the treatment itself as you do for the survey.

MEMBER FISCHER: I just have one comment. So as I understand it, the other thing that concerns me is that folks who refuse that's no longer an exclusion and it seems like the rationale was to incentivize facilities achieving higher completion rates.

But there really isn't a lot of specific guidance given to facilities as to how to do that. It just kind of says make efforts to increase the number of patients and I think there's an art to that and that's a little bit difficult.

You know, in retrospect one way to try to incentivize that would have said, you know, someone has to refuse twice or three times in a certain time period.

This is how we've done it actually in the VA with things like this where you try to incentivize high completion rates but not given broad brush punitive measures, again, to a facility for a low completion rate when sometimes there's a limited ability of a facility or a specific provider to increase that, to increase someone completing a survey.

That's how I understand the change. I mean, that would be my concern.

MEMBER DALRYMPLE: And I think that's an important point. I think patients have the right to refuse completing surveys and if you give kind of guidance, just make reattempts with no limit.

So I like your example of you cap the number of attempts so that patients really do have the autonomy to not complete surveys they wish not to complete.

I do think we should try and move on to reliability unless other committee members - Lisa?

MEMBER LATTS: Can I just make one comment about the refusals? I do think that if you do use that as an exclusion it is an opportunity to game the system on the part of the facility because they could say, oh, are you refusing - yes, you're - you know, I mean, there are ways to encourage people to do it and there are ways to discourage people to do it.

And I think with the understanding that the results shouldn't be 100 percent because you are - you know, people are going to refuse. If there is an abnormally large rate of refusals that suggests something that should be looked at.

MEMBER MADDUX: I completely agree. That's why a more nuanced approach is having a set number - a higher number of refusals, not just yes/no but the person had to refuse twice or three times during a certain time period, which we've tried to do.

Again, as Laurien touched upon, keeping it patient centered, especially given the number of surveys patients are being asked to

complete.

MEMBER DALRYMPLE: I was just looking at the time. Should we move on to reliability testing?

CO-CHAIR ANDERSON: Can we take a vote, please?

MEMBER DALRYMPLE: Oh, we haven't gone to discuss the reliability testing. So we will go through this. The developers do provide reliability testing for years 2013, 2014 and 2015. I am assuming that the data presented in 2015 is a typo.

So we will assume the reliability is actually .926 to .93. So and that is looking at between facility differences. There is distribution of reliability also provided.

From my perspective, the one issue that was not addressed for reliability is whether it differs by facility size which you would potentially expect it to because smaller facilities have a smaller annual. I think the committee should discuss that first and then if

we need developer feedback we will ask for it.

But did anyone have any comments on the reliability testing or the distribution of the reliability as presented? Should we move on to discussing the validity?

Okay. So the validity testing - I know there were a number of pre -

CO-CHAIR CROOKS: I think we -

CO-CHAIR ANDERSON: Sorry, Peter. It's time for a vote.

CO-CHAIR CROOKS: So we vote on specs and reliability together in one vote, and then we go on to validity, correct?

MEMBER DALRYMPLE: May I ask a question then of the developer? Do you have any reliability and information with respect to facility size? Do smaller facilities have lower reliability as compared to large dialysis facilities?

DR. BRAGG-GRESHAM: So I did not look at that specifically but based on, you know, the equation for reliability that would - you know,

that would be expected.

MS. OGUNGBEMI: If there are no other comments from the committee we are going to go ahead and vote on reliability for Measure 0260. This includes precise specifications and testing.

The options are one, high; two, moderate; three, low; and four, insufficient. Voting is open.

MS. OGUNGBEMI: Results are for Measure 0260 on reliability 15 percent high, 40 percent moderate, 45 percent low and 0 percent insufficient. So Measure 0260 passes on reliability.

CO-CHAIR CROOKS: I'd just like to comment that I think this is the wrong process, that if we're voting on specs alone it probably wouldn't have passed.

But if you put specs and reliability together then everybody's thinking oh, the reliability looks good so they vote yes. And I think this is a wrong result because of the way we vote.

MS. OGUNGBEMI: So I need to make a correction. It is - it falls in the gray zone.

CO-CHAIR CROOKS: It falls in the gray zone? Okay.

MS. OGUNGBEMI: Yes.

CO-CHAIR CROOKS: But my comment still stands. I think the specs could be terrible but the reliability could be good. You know, it doesn't -

MEMBER DALRYMPLE: Can I clarify with the NQF staff? Doesn't validity testing also incorporate considerations of the specifications in some way because you can argue when you start creating exclusions that maybe even on face validity don't make sense then there can be a validity failure as well.

I agree with you, we often vote on the reliability testing in this section. But I think validity is another opportunity to address this.

MR. LYZENGA: It is. The specifications in the reliability section are really intended to get at whether the

specifications are precise, understandable, can be implemented consistently whereas, you know, as you said, have another opportunity in validity to talk about whether the specifications reflect the evidence provided and truly reflect, you know, an accurate view of quality as specified.

MEMBER FISCHER: Could I just ask a question to the NQF staff? Could you, just for my understanding, re-explain or redefine what gray zone means? I don't recall entirely.

MR. LYZENGA: So this is something that emerged out of some work that we had -- a consensus task force. We wanted to acknowledge places where there was not clear consensus across the committee. When the measure does not receive in excess for any particular criterion in excess of 60 percent for below 40 percent, it falls in the so-called gray zone.

In that case, the measure does move forward to - for consideration against the remaining criteria. But I believe we put it out for comment and then we ask the public to give us

feedback on it and then take a revote, I believe, after that to just sort of confirm or give another go at the vote after we receive some comment on that particular measure.

CO-CHAIR CROOKS: Revote would be by - just so I'm clear, the revote would be by this committee again.

MR. LYZENGA: The same committee, yes.

CO-CHAIR CROOKS: Okay. Thank you.

MR. LYZENGA: Considering, you know, again, any public comment that comes in.

CO-CHAIR CROOKS: Okay. I just wanted to make sure I understood the implications. Thank you.

Okay. Let's move on to validity then.

MEMBER DALRYMPLE: Okay. So for validity testing we actually have a fair amount of data we can look at with respect to what the developer provided with us.

First, we'll look at the linear mixed model that is presented. My understanding is in this model they looked at patient level quality

of life scores for each scale as the dependent variable and the facility completion rate was the main independent variable.

The models were adjusted for patient level characteristics, age, sex, race and diabetes. Facility clustering appears to have been accounted for but I think we are missing some information.

There's a blank in the description of the methods. A compound co-variance structure was used.

So we can look at the results of this. The developers state they found a significant and positive association between facility completion rates and quality of life scores for these scales and the MCS and PCS.

However, I did not find the interpretation of the estimates to be intuitive. So if other committee members were able to interpret these estimates I think that would be helpful.

If no one on the committee was

entirely clear how we should interpret the estimates then I thought this would be helpful to maybe just have the developers in one sentence state for us how we should interpret the estimate provided for, let's say, the MCS outcome or the MCS estimate.

MS. WITTEN: Jen? Jennifer?

DR. BRAGG-GRESHAM: Sure. I'm happy to go through. So interpreting facility level co-variance is always a little tricky. So we need to think about because the outcome was at the patient level basically this estimate applies to all the patients in the facility. So we set up this first table to be the estimate of the effect comparing, let's say, a facility that has 90 percent completion - or sorry, 80 percent to one that has 90 percent.

So we're saying if the facility has a 10 percentage point higher completion rate then you would expect all of the patients in that facility to have, you know, the estimated difference in their score. So in this case,

they're all positive.

So you'd say, you know, if you want to look at the first one, symptoms - so in a facility that has 90 percent completion rate versus one that has 80 percent completion rate, all of their patients on average had a .21 higher symptoms score.

You know, so we know that's a small effect. But I think it's important that it's positive and it was significant in terms of, you know, P value here. Does that help?

MEMBER DALRYMPLE: It does help. So I just want to clarify. So for a 10 percent higher completion rate, so comparing someone who has a 90 percent versus 80 percent facility completion rate, the average patient level changed and the MCS would be .08. Is that correct?

DR. BRAGG-GRESHAM: Correct. And it wouldn't be changed. It would be - right. Different. Right.

MEMBER DALRYMPLE: I'm sorry?

DR. BRAGG-GRESHAM: It would be a different -

MEMBER DALRYMPLE: On average .08 higher?

DR. BRAGG-GRESHAM: Correct, yes.

MEMBER DALRYMPLE: Okay.

DR. BRAGG-GRESHAM: That is correct.

MEMBER DALRYMPLE: Okay. If the committee members feel comfortable with that we can move on to the other data presented. There were data looking at the exclusion analyses.

The exclusion for age I'm sure none of us who work in data are surprised that reported age and calculated age sometimes don't match up. So I think that's okay. It's real life.

If you then look at patient characteristics by exclusion criteria you can see we have information with respect to sex, race and diabetes for each of the exclusions including cognitive impairment or language barriers or in the facility less than three months.

We then go on to have information

provided, looking at the odds of completed versus refused or the odds of completed versus excluded with respect to age, sex, race and I believe this is year that the survey was completed. It's reported as year per year.

But I notice there was a lot of pre-committee comment and I had similar feelings that it wasn't clear to me that this information was helping me think about validity and potentially even started to make an argument that there may be a case mix issue or need for adjustment and I saw others raise those concerns.

So although this was presented in the validity testing with one purpose I think it's probably more important that we as a committee discuss what our inferences are when you look at whether the odds of completing versus refusing or perhaps completing versus exclusion are different, depending on your age, sex, race and the year.

So do committee members want to discuss these? I know many people submitted

comments. So it may be helpful to just discuss those more broadly. And Connie and Lori, if you want to lead with that discussion.

CO-CHAIR ANDERSON: I think you've stated it very well. Comments? Questions for the developer? Conference question? All right. Shall we vote?

CO-CHAIR CROOKS: I'd just like to back up for a second, Lori, into the - and I may have missed the - so the opportunity to discuss this.

But I felt they were trying to make a case that this is valid because units that do more of these have - their quality of life scores are higher actually as a - to prove validity and that's questionable because patients who - you know, units that have a lot of patients that complete it may have healthier patients and more mentis compos patients to do it.

So did you discuss that in your analysis or is that a - do you think that's a valid -

MEMBER DALRYMPLE: And are you referencing the - I guess what's number three, in order to assess if the exclusions are needed. We assess the association between completion versus refusal analyses or which analyses are we specifically discussing, just so I can answer correctly?

CO-CHAIR CROOKS: Do other committee members have issues with trying to prove validity that way or am I perhaps misreading it or over reading the -

MEMBER DALRYMPLE: I mean, I can tell you when I was looking at this I guess how I personally felt was this doesn't help me understand per se whether exclusions are needed because it's showing there are differences between those who complete the survey and those who refuse the survey, and refusal is now part of your denominator.

Yet there's no case mix adjustment. So, for example, if we look at number three, the odds of completing versus refusal and you look at

age, those who are older are more likely to complete than refuse.

Those who are male are less likely to complete versus refuse. If I'm interpreting this correctly please other people jump in. And then year - if this is year of the survey, does anyone know if this is year per year of the survey? That's how I -

DR. BRAGG-GRESHAM: That's correct.

MEMBER DALRYMPLE: Okay. Thank you. So as the year increases there's an increasing odds of completion versus refusal.

So then you can also look at the next model, which is different facility completion percentage points with respect to percent male or race and also see differences.

So at least when I looked at this table and perhaps we should give the developers a chance to explain it to us this didn't help me think about validity as much as is case mix adjustment needed because of different populations within different facilities if

refusing is now in the denominator.

So for me personally it raised more questions than it answered, Peter. But perhaps I didn't fully understand the intent.

There's also completed versus excluded but the part I was most interested was completed versus refused because of the denominator changes.

So perhaps we should give the developers the opportunity to inform us how they intended us to think about it in case we're missing the primary goals.

CO-CHAIR CROOKS: Does the developer wish to comment?

MEMBER DALRYMPLE: Jennifer?

DR. BRAGG-GRESHAM: Beth - oh, so you went ahead and just - so the issue here is that we were unable, you know, to go in and audit the patients in KDQOL complete.

So in discussions with NQF, this was data that we had that we hoped would, I guess, get at the validity question.

So we wanted - and I think, you know, this is an exclusion so this - I think we just wanted to be sure here, you know, that the case mix - you know, we wanted to know if the case mix was important in looking at this.

Beth, was there another reason that -

MS. WITTEN: Well, one thing that we didn't have the opportunity to do was to go into clinics and see if people truly did do what they said they did.

Same thing is true for the depression screen, for the pain screen. We don't even know for sure that some of the other clinical measures like Kt over V are measured the same way every time. We're trying to do the best we can and assuming that people aren't lying - people aren't gaming the system.

This is not currently publicly reported. It's not something that a clinic's income is based on. So there's not maybe as high a need to lie on this particular measure as there might be on something that they could have their

funding cut. I don't know if that answers the question or just goes off target.

MEMBER SOMERS: I think that I have to agree with Laurien because I think the data that's been presented here would speak towards the need for some case mix adjustment because depending upon the population you have shown data that there are differences.

MS. WITTEN: So this is case - you're asking for case mix adjustment on whether you completed or didn't complete, not on the scores, because there is actually in KDQOL complete and I think Fresenius and I assume DaVita and other providers there is case mix adjustment.

The outcomes and practice pattern is set up for the scores. Case mix adjustment based on age, gender and diabetes status. We're just looking at the process measure of did you complete it, did you not complete it.

MEMBER ZARITSKY: That's with the data you have here, right, saying that you need to adjust for completion.

MEMBER DALRYMPLE: But the measure is not case mix adjusted.

MEMBER ZARITSKY: Right.

MEMBER DALRYMPLE: But the data presented suggests it should be.

MEMBER ZARITSKY: Suggests it should be.

CO-CHAIR CROOKS: Alan?

MEMBER KLIGER: I agree.

CO-CHAIR ANDERSON: Is there any further discussion or questions for the developers? Are we ready to call for the vote?

MS. OGUNGBEMI: We are now voting on validity for Measure 0260. The options are one, high; two, moderate; three, low; and four, insufficient.

Voting is open. We are waiting on one more vote. Could everyone just try and use their clickers one more time, please? Thank you.

MS. BAL: Lori, we got your vote so you do not need to send it again. Thank you.

MS. OGUNGBEMI: Thank you. Results

are in. Zero percent high, 10 percent moderate, 80 percent low and 10 percent insufficient. Measure 0260 fails on validity.

MR. LYZENGA: So given that validity is a must-pass criterion that means the measure does not pass. We could still continue a bit of discussion if we want. I think we have the time in case we wanted to provide some feedback for the developers if they wanted to bring the measure back at another time.

Is there any additional feedback on any of the remaining criteria, usability or feasibility or some of these other things you've discussed with respect to reliability or validity or importance that you'd like to pass on to the developer for other future efforts?

MS. SAMPSEL: And let me tease that out a little bit more because as a maintenance measure remember there's more importance on feasibility and usability and really where this measure is going.

You know, typically we wouldn't have

those discussions. We're not going to vote on them.

But in case there is additional information that might help the developer, if you had noticed things in your preliminary reviews and evaluations it might be helpful at this time. It would just be a matter of putting it out on the table so the developers would know how to respond.

CO-CHAIR CROOKS: Laurien, did you want to summarize what you thought about feasibility and usability?

MEMBER DALRYMPLE: In terms of feasibility this seemed like a feasible measure and as noted by the developer their in talks with CROWNWeb so that would, obviously, increase the feasibility quite a bit if KDQOL data was entered into CROWNWeb.

But my understanding from the developer is a number of independent dialysis organizations already participate in the KDQOL complete and the LDOs tend to have their own

system. So from my perspective, this is a feasible measure to report.

In terms of usability and use, it's planned per the developer to be used in public reporting and current uses is quality improvement with bench marking within the KDQOL complete and also some internals to specific organizations.

Did we have any committee pre-evaluation comments that were relevant to feasibility or usability? I'm trying to look on the screen because those may be the most helpful.

But I don't recall there being substantive concerns about either of these criterion. So usability and use. Would it be possible just for us to give all of those comments on to the developer?

MS. SAMPSEL: Those are already shared with the developer.

MEMBER DALRYMPLE: Okay. So I think we probably don't need to read them aloud.

CO-CHAIR CROOKS: Okay. So I think we're at the point where we can take a break.

Back in, what, 15 minutes? Ten minutes? What do you suggest? Fifteen minutes. All right.

(Whereupon, the above-entitled matter went off the record at 10:46 a.m. and resumed at 11:04 a.m.)

CO-CHAIR CROOKS: So as long as we're a little ahead of schedule, let's keep pushing it along and see where we can get to before lunch time. And at 11:30 we have a break for public comments. Before lunch? Okay.

So we've decided to follow the order on the agenda, rather than the order that they were put out initially. So we're going to move to measures, the two measures on vascular access, first 2977, standardized fistula ratio, and then the catheter rate.

So John is here to present for the developer. Thank you.

DR. SEGAL: Thank you very much for the opportunity to address the group. I'm John Segal. I'm a nephrologist. With me is Sehee Kim who is our statistical guru who did much of the

modeling for our measure. And I'll read our opening statement.

The CMS Fistula First Catheter Last initiative has helped establish significant gains in fistula rates over the last decade. Although the literature continues to highlight the general benefits of fistula compared to grafts or catheters, there's been a growing concern in the dialysis community that in some subsets of the dialysis population increased use of grafts and less emphasis on fistula may be appropriate with continued emphasis on reduction in the use of tunnel catheters.

In response to these concerns, CMS called for a technical expert panel that was convened in April of last year. The group acknowledged that while grafts play an important role in vascular access, a fistula and catheter measure would be both complementary and sufficient and that there was no substantial gain in having a third measure to evaluate graft use. In addition, the TEP recommended that we look at

risk adjustment strategies for fistula rates, thereby accounting for patients that may be more likely to end up with a graft.

Both vascular access measures that will be discussed today represent substantive revisions that reflect input from the TEP and are intended to replace the existing measures that were first endorsed in 2007 and then re-endorsed in 2012 and last year.

I'd like to highlight the five major changes for the fistula measure. Those include risk adjustment for factors that are associated with decreased likelihood of fistula success; inclusion of all eligible hemodialysis patients, not just Medicare beneficiaries since the measure is now specified to be calculated from CROWNWeb; inclusion of patients in the first 90 days of dialysis who were previously excluded as this is a critical time for access planning and placement; including only patients with a fistula that are counted in the numerator; fistula combined with another access type such as a

catheter is no longer counted as it was in the currently endorsed measure. And lastly, exclusion criteria have been added to the measure for conditions associated with the limited life expectancy where fistula may not be the appropriate choice for access. Thank you.

CO-CHAIR CROOKS: One clarification, on the inclusion or exclusion or Medicare only, it now is Medicare only or it was Medicare only before?

DR. SEGAL: In the past, it was -- the currently endorsed measure is designed to be calculated either using Medicare claims or with CROWNWeb, but it's typically for Medicare only.

CO-CHAIR CROOKS: So as it stands now, this measure will only apply to Medicare-covered patients?

DR. SEGAL: The measure that we're discussing today applies to all patients.

CO-CHAIR CROOKS: Will be all, so it's now broadened out for all.

DR. SEGAL: Exactly.

CO-CHAIR CROOKS: Okay. Thank you. Okay, so Franklin knows he's sitting quietly on the sidelines. Thank you. Elizabeth Evans, Alan Kliger, and Debra Hain are our primary discussants. Who wants to take the lead? Dr. Kliger.

MEMBER KLIGER: Okay, so this has been intended to join in the series of standardized rates of all sorts of things that we're currently measuring. It's just interesting to point out at the outset that as a standardized rate that by definition we're always comparing current performance with what expected performance would be, rather than an absolute rate. And we brought this up before, but I just want to raise that again for anyone who may want to make any comments about that.

And as we just heard, the numerator is the adjusted count of adult patient mumps, using an AV fistula as the sole means of vascular access. The denominator, all patients 18 years old, as of the first day of the reporting month,

on maintenance hemodialysis in center and home hemodialysis.

And the denominator exclusions and I'll just -- I want to just pause and go over those just now. We'll talk about that again when we talk, I guess, about the validity, but I want to highlight some of specifics here. It's excluding children, 18 years or younger. It's excluding peritoneal dialysis and it excludes patients with incent or home hemodialysis but less than the complete month at the same facility. So it's really just that one month window at that same facility.

In addition, the folks putting this together specifically wanted to eliminate patients with a catheter that have a limited life expectancy. And the way that they define that was patients under hospice care in the current reporting month; patients with metastatic cancer in the past 12 months; patients with end-stage liver disease in the past 12 months; and patients with coma or anoxic brain injury in the past 12

months.

And rather than do case mix adjustment, it sounds like you guys decided to make those exclusions because of the variation in the percentage of those patients across the spectrum that there were different distribution of those patients at different dialysis facilities, so chose to make those exclusions rather than adjust for the presence of those diseases.

So if you look first -- if we look first at the evidence to support the measure, I'll make some comments, but then I'll be really interested to hear what everyone else thinks about this. There's really clear evidence as the developer just said and it continues to grow that there's a relationship between AV fistula use and better outcomes and fewer complications. I note, however, that the studies are all retrospective and observational studies and while those are obviously very important to help us think about problems, they are retrospective and they're on a

population level. And so I think we just have to be conscious that that's the case.

And this time for the first time, we're being asked to exclude these classes of patients that I discussed, but there is no discussion of other potential subsets of patients who might also perhaps not benefit from a fistula; for example, patients who make a choice based on their own judgment of what access they should have. Now, we could make inferences based on the data that's been published, but unless the developer can help, I don't remember any studies that specifically looked at patient choice and looking at that subset of population that makes a decision to use something other than a fistula. And we all know that there are, of course, such patients that are there. So it's just unknown. We don't really know that. The frail elderly or patients with very poor vascular access, very poor potential vascular structures to construct an access.

So at least to me, the exclusions seem

very reasonable and appropriate and I, for one, was really glad to see you exclude those, but I wonder about other potential exclusions that you haven't considered.

In any case, in terms of looking at overall the data to support the measure, I think the data are strong, but since they are observational and retrospective, I have just -- I wouldn't rate it as the very highest level of data.

So let me just ask others in terms of specifically the evidence to support the measure, if there are other comments.

MEMBER GREENSTEIN: I just want to make a comment to what you said, Alan. I think that you could also make the point to exclude those patients that the access surgeon says it's impossible to create fistula graft, because otherwise if you don't exclude them, you're going to be including them in your denominator all the time.

And there are patients like that. I

mean I face that every once in a while when a patient is like you said, elderly, 80 year old, and has really poor veins and, you know, to put a graft in this person, the skin is going to just rip apart every time you stick the saline with a hemocatheter.

MEMBER KLIGER: Yes. So perhaps I can ask the developer, did you examine the distribution of those patients across all? Is there even distribution or not of patients where the potential of establishing an access is exceedingly low?

DR. SEGAL: The short answer to the question is no, we don't have that data available, but the TEP spent an enormous amount of time discussing patients who had exhausted all of their anatomic options for access and through this uniform agreement that that would be an important exclusion criteria for this measure, where we got the TEP was unable to reach consensus in how best to implement that concept or construct. And so there was discussion about

an attestation from the facility and who should make that attestation and how often should it be done and we couldn't reach an agreement about a best process to put into place.

What I will say is that with vascular access data now accumulating in CROWNWeb, I see that in the future we might be able to go and look back and say oh, this patient's had three failed fistulas and two grafts and now they're dialyzing with a catheter and so we may be able in the future to look at people who have gone through multiple accesses or exhausted their options to be able to potentially exclude from. We just don't have that depth of data available to us right now.

CO-CHAIR CROOKS: But if one argues that they're evenly distributed through different facilities, maybe that's not all that important.

MEMBER KLIGER: Right, but Peter, we don't have the evidence for that --

CO-CHAIR CROOKS: Right.

MEMBER KLIGER: -- so we really don't

know.

CO-CHAIR CROOKS: Right.

MEMBER GREENSTEIN: I don't think they are evenly distributed. Just from my own experience from working in the Bronx, I mean I know there's one facility that -- this facility has mostly nursing home patients and they're train wrecks in terms of access.

MEMBER KLIGER: In any case, that probably comes to the validity discussion, but in terms of the -- any other concerns or questions or comments about the evidence?

CO-CHAIR CROOKS: So I think we can vote on evidence then. Let's put the question.

CO-CHAIR ANDERSON: Are there any other comments from the other reviewers other than what Alan --

MEMBER EVANS: Sorry, speak. Intermediate clinical outcome measure. Okay. That was all.

MS. OGUNGBEMI: We are now voting on the evidence for measure 2977, hemodialysis

vascular access standardized fistula rate. The options are 1, high; 2, moderate; 3, low; and 4, insufficient. Voting is open.

(Voting.)

MS. BAL: Could everyone just vote one -- I'm sorry, never mind, 19 is the right number. Thank you.

MS. OGUNGBEMI: The results are for evidence: 26 percent high; 74 percent moderate; 0 percent low; and 0 percent insufficient, measure 2977 passes on evidence.

MEMBER KLIGER: Okay, thanks. We talk about the performance gap. It continues to amaze me as I look at the data that you presented that despite evidence of -- despite shining a light on this for the last at least nine or ten years, that there continues to be very convincing evidence for a performance gap and for disparities in care both. And the data we're all presented here and you've all had a chance to see that, but it does indeed look like the interquartile differences in measure performance

from CROWNWeb are substantial and that there are demonstrated disparities by age, sex, ethnicity, race, political party.

So I think that you did deal with those issues and we have clear evidence of a performance gap and disparities. So the other two major reviewers, can I ask you if you have any other comments? And then anybody else? Okay.

CO-CHAIR ANDERSON: All right, are we ready to vote? Good.

MS. OGUNGBEMI: We are now voting on performance gap for measure 2977. The options are 1, high; 2, moderate; 3, low; and 4, insufficient. Voting is open.

(Voting.)

MS. OGUNGBEMI: Results are for performance gap of measure 2977: 53 percent high; 42 percent moderate; 5 percent low; and 0 percent sufficient. Measure 2977 passes on performance gap.

MEMBER KLIGER: So we come to

reliability. The developers measured reliability by calculating the inter-unit reliability. This is a measure we're all familiar with. We've talked about that our last round and we will for other measures here as well.

And here, the inter-unit reliability was 74 percent, .74, suggesting that three quarters of the observed change was -- can be assessed by this variable and noise is the other 25 percent. So by this measure, that's a pretty darn good test of reliability.

First, do any of the other two developers have any questions about that? Not developers, I'm sorry, reviewers and others.

MEMBER DALRYMPLE: Were we going to discuss specifications first or were we going to do that next?

MEMBER KLIGER: I wanted to do that after this.

MEMBER DALRYMPLE: After the IUR, okay.

MEMBER KLIGER: Yes. Okay, so then

when we get to talk very specifically about these specifications, let me just open that and ask people for their comments. I've actually already made mine. So first, the other two who were major reviewers, any comments about the specifications?

MEMBER EVANS: I had issues with really the clinics that have that high elderly patient population that have no vessels and is that going to skew their numbers with that for that validity for that particular clinic because they do live in certain areas and they will attend a higher percentage at certain clinics.

MEMBER KLIGER: Lorien, did you have something?

MEMBER DALRYMPLE: So I had several questions about the specifications primarily focused on the exclusions.

The first point I guess I would make is my understanding then of the exclusions is they can truly only be applied to Medicare recipients, but this measure includes all

patients within a facility. So it's not clear to me if there's some accounting in the model for proportion of patients represented by Medicare within the facility to try and offset arguably the bias in your ability to capture an exclusion so we could ask the developers to answer that.

And then although --

MEMBER KLIGER: Can you stop just with that? Let's just ask them that question first.

MEMBER DALRYMPLE: Sure.

DR. SEGAL: Sure, that's a great question. So when we look back to look for exclusion criteria, so really we're looking for people that have either hospice or Medicare claims.

So when we look back, we find that 84 percent of patients have at least 1 Medicare claim in the last 12 months. So that you're correct, there are 16 percent of people that we have no information that these exclusion criteria will be extrapolated to. But here's the key point, when we look at facilities as a function

of what proportion of Medicare patients do they have, we broke it into essentially three groups: facilities that have less than 50 percent Medicare patients. Those are very, very few in number. We split it then to 50 to 75 percent Medicare patients and 75 to 100 percent of Medicare patients in the facility.

And when we looked at whether these adjustments that we're making in the model change our standardized fistula rate, we found no difference. So what that means is at the individual level, having individual patient level doesn't seem to have an impact on the facility model. So the facility standardized fistula rate didn't change when we had a small group of patients that either had or didn't have comorbidity or exclusion criteria.

MEMBER DALRYMPLE: And did that finding surprise you? That in facilities with extremes such as less than 50 percent Medicare patients that they -- that the estimate wasn't influenced by --

DR. SEGAL: Sorry, we're not talking about the facilities. Since there are so few facilities, there were less than 50 percent. So in the 50 percent or more -- so the vast majority of facilities, there's very little difference when you have a few patients that don't have that information.

So I interpret that to mean that our model is relatively robust and that having a few patients one way or the other isn't going to sway the overall impact of the facility analysis.

MEMBER KLIGER: Anyone else have comments about these exclusions or anything about these specifications?

MEMBER DALRYMPLE: I had a separate comment about the exclusions that I thought maybe other committee members would have thoughts on, and if not, we could go to the developers. But when I looked at that ICD-9 specifications it was unclear to me if they fully captured the picture of, for example, metastatic cancer or what was intended by that, for example. I think we have

ICD-9 codes for ALL and AML, but I didn't see any for lymphoma.

So again, how were ICD-9 codes selected to represent what is or is not metastatic cancer and then fairly select codes were selected to end-stage liver disease, whereas the number of codes that include cirrhosis were left off and perhaps that was appropriate and intentional but the process for selecting ICD-9 codes was unclear to me, as was the process for ICD-10 crosswalking, if that was simply done using GEMs or if there were actually coding expertise used to supplement that ICD-10 crosswalk.

DR. SEGAL: So we used HCC groupers for the specific ICD-9 codes. So we didn't go in and one by one isolate ICD-9 codes for these diagnoses. So there are large categories for metastatic cancer, for liver disease. And so we just used those as a starting point and we didn't really modify them to add or take out from those groupers.

MEMBER DALRYMPLE: For the ICD-10 crosswalk, you used an ICD-10 version of the HCC essentially or how was that done?

DR. SEGAL: Right. We have a crosswalk process that moves those over. So obviously, since all of the modeling that we've done has been based on ICD-9 codes, we haven't had a chance to -- we are not yet able to test the ICD validity in terms of that crosswalk.

MEMBER KLIGER: In terms of racial differences and gender differences, the specifications do not state anything about adjusting for that. So you're not trying to adjust for those and would that be appropriate not to adjust?

DR. SEGAL: Correct. In the current model, we are not adjusting for race or sex. It was -- after reviewing the literature, so for example, there are some studies that report that women have lower rates of fistula than men. Some of those studies looked at forearm fistulas and other studies looked at upper arm fistulas, show

that there were no differences. And so we are trying to be cautious that we don't adjust for a factor that may represent a disparity in care as opposed to a true biologic difference.

CO-CHAIR CROOKS: I would agree that's appropriate. Other comments on specifications?

CO-CHAIR ANDERSON: To the measure developer, when you were looking at it in your TEP panels, did you consider people that have had vein mapping, and to Stuart's comment, that were ineligible for a permanent access as a means of having an exclusion criteria for these fragile patients that don't -- or aren't going to have an access?

MEMBER GREENSTEIN: Can I add on top of that? The IV drug abusers, dependent upon where you live, they are the most challenging patients in the world. So shouldn't they be possibly excluded also then?

DR. SEGAL: For those, we are -- those are all considered in our adjustment for the model, so we adjust for older age. We adjust for

nursing home status as a marker potentially for frailty. We do adjust for IV drug use. So we did not specifically discuss at the TEP. I don't recall issues like vein mapping in particular as a way of identifying people who might be excluded from the measure outright.

MEMBER GREENSTEIN: I personally would not use vein mapping because every vascular lab is going to be totally different in terms of -- it's very technician-specified. I know I just get vein mapping, not for the veins, but should look at the arteries actually.

CO-CHAIR CROOKS: Okay. Let's vote on reliability and then I guess because of the overlap with specifications in the validity, some issues may come up there as well. I think we can vote on reliability at this point. IUR was 74 percent.

MS. OGUNGBEMI: We are now voting on the reliability of measure 2977. Options are 1, high; 2, moderate; 3, low; and 4, insufficient. Voting is open.

(Voting.)

MS. OGUNGBEMI: Results are for reliability of measure 2977: 21 percent high; 79 percent moderate; 0 percent low; and 0 percent insufficient. Measure 2977 passes on reliability.

MEMBER KLIGER: Okay, so then going along to validity, the developers correlated this particular measure with standardized mortality rate and standardized hospitalization rates and as I'm sure no one was surprised by in this room, the correlations were there and were good.

They did some additional validity work using regression models and I can only say that the validity testing, at least as proposed, is reasonable and is strong. So I believe the validity there is high.

In terms of the specifications or exclusions and the validity testing, let me just again open that to any other discussion. First, from our other reviewers, in terms of overall validity, and specs and then I'll open it up for

everybody.

MEMBER EVANS: I do want to point out one thing from the TEP that they put in a little caveat that it was recognized that some patients on dialysis will need to have a graft or even a catheter. As evidence, the CMS AV fistula targeted the facility level is 68 percent rather than 100 percent which recognizes a third of patients will require a different type of access.

They do say the TEP recognized that while fistulas are preferred, an unintended consequence of a fistula measure that doesn't account for a patient's overall health status could harm patients by subjecting them to fistula surgery.

MEMBER KLIGER: Okay, any other comments from anybody? Questions?

MEMBER DALRYMPLE: I had a question for the main reviewers. What did you think about the percent excluded? Was it what you would have expected or -- I'll give you my bias. It seemed low to me to be honest. I had anticipated a

higher percent exclusion.

MEMBER KLIGER: So I shared your surprise. I thought it was low, but I guess that's reassuring to me.

MEMBER DALRYMPLE: If I can ask the developers, did you think the exclusions were what you would have anticipated among this population and is there any concern that there are unselected HCC categories or something else accounting for the low percentage of exclusions based on the descriptions?

DR. SEGAL: I agree, when I first saw those numbers, it was a bit lower than what I was anticipating finding as well, but we didn't -- after doing a couple of different analyses, to make sure that we think we're really measuring what we're measuring, we think we are. And so there again, there is some range. There are obviously facilities that have much higher proportion of patients that are excluded, but overall, it's relatively low.

MEMBER KLIGER: And again, to me the

issue again is that I think the exclusion criteria that you picked are defensible and are real. I'm just concerned about as we had some discussion, other subgroups that might not be so evenly distributed and might likewise be considered for exclusion.

However, I think that at least in my mind, it's likely that the patients that you've chosen to exclude are the largest bulk of those that we would end up seeing as an excluded link.

DR. SEGAL: One other comment about the exclusions. When we first looked at exclusion criteria, we looked at them and -- blinded to their access type. So what we found is many patients who met exclusion criteria were dialyzing with fistula. So they were in hospice. They had a fistula or they had metastatic cancer and they had a fistula. So when you narrow it down to patients who just have a catheter, it was a smaller number.

CO-CHAIR ANDERSON: Any further questions? All right, we're ready to vote.

MS. OGUNGBEMI: We are now voting on validity for measure 2977. The options are 1, high; 2, moderate; 3, low; and 4, insufficient. Voting is open.

(Voting.)

MS. OGUNGBEMI: Results are for validity: 32 percent high; 68 percent moderate; 0 percent low; and 0 percent insufficient. Measure 2977 passes on validity.

MEMBER KLIGER: Okay, feasibility. Feasibility, again, just to remind everybody, measures the logic of the specifications, the required data that are available and the burden, whether it can be implemented without burden.

These data -- we've had lots of experience capturing and examining these data and so there is nothing new here. So I have no other comments in general about the feasibility, but invite anybody else.

CO-CHAIR ANDERSON: No further comments. Let's vote.

MS. OGUNGBEMI: We are now voting on

the feasibility of measure 2977. The options are: 1, high; 2, moderate; 3, low; and 4, insufficient. Voting is open.

(Voting.)

MS. OGUNGBEMI: Results are 84 percent high; 16 percent moderate; 0 percent low; and 0 percent insufficient. Measure 2977 passes on feasibility.

MEMBER KLIGER: Okay, flying along here, when we talk about usability and use, again to remind everybody, this is the extent to which audiences including consumers, purchasers, providers, policy makers, maybe even doctors, use or could use performance results for both accountability and performance improvement activities.

The comments that most people said is that these have been used. The fact that we're using statistically and standardized rates is the issue that at least some have raised, whether or not this ought to be calculated as a standardized ratio or whether they ought to be calculated as

an absolute amount is something I just want to open and ask people for their thoughts about that.

Other than that -- other than moving to a standardized ratio, the usability has been really clear before in any case. So in terms of usability and use, let me open first to the other major reviewers and then to everybody else. You guys have a comment about that? And then anybody else.

MEMBER NARVA: I assume this has a relatively low exclusion rate, so that reduces the need to have a standardized -- make a standardized ratio. Is that true?

MEMBER KLIGER: Ask the developers that question.

DR. SEGAL: If you had a higher exclusion rate, then there would be greater need to have a standardized ratio. Is that ==

MEMNER KLIGER: Let me just clarify to make sure I understood actually the first part. So this measure is calculated as a rate, not as a

ratio. So we felt that was important so that facilities are used to seeing their fistula rate.

And so we didn't want to change the game for them midstream and say now it's a ratio and you don't exactly know what your percentage is when it's adjusted. So I'm not sure if that changes the question, but the facilities will have a rate as expressed as a percentage that is reported.

MEMBER NARVA: My question was just if there were a higher exclusion rate, it would suggest that there's more opportunity to have variation between units based on what the population is and more need to have -- express it as a ratio. So this has a low exclusion rate, so the need to even think about doing it as a standardized rate is not as great. Is that -- do I get it? Is that fair to say, the ratio?

DR. SEGAL: I think sometimes we think about rates and ratios as a function of event occurrences, so that for at least the way we did our standardization, we felt that the rate for

this measure was most appropriate because access is a frequent -- you know everybody has got an access as opposed to other measures which have more rare events where sometimes a ratio is more helpful to look at that.

MEMBER KLIGER: I apologize that I introduced that confusion, so I'm sorry. Indeed, it is a rate and not a ratio. Thank you.

CO-CHAIR CROOKS: It says that CMS will consider using this and then return the other related measures. Are you beyond considering -- is this definitely the plan to use this?

DR. SEGAL: I can't speak for -- well, Joel can -- CMS can speak for CMS.

CO-CHAIR CROOKS: Assuming it's endorsed, is it a pretty sure thing it will be used?

MEMBER KLIGER: Can we invite you to speak? You have to leave your Social Security Number at the door though.

DR. ANDRESS: Understood. I'll do

that on my way out. Okay, so we developed these measures specifically with the intention of updating the existing vascular access measures. When you look at them, they were developed in 2007 and we see this as a natural progression of those measures.

Nothing is ever set in stone. I have to caveat that every time someone asks me about the QIP obviously. There's a rulemaking process. These measures in order to go into the QIP will have to go to the MAP first and we'd have to get feedback there and it would have to go through rulemaking.

We also have a process in place now for including measures on Dialysis Facility Compare, and we would have to go through that before it was set, but I think we developed these with the intention that these would be our vascular access quality measures in the future. Whether or not they actually become so depends on a great deal of action in the coming year or two.

MEMBER GREENSTEIN: I have a question.

So I'm not clear then, what is the role then? Because you will have dialysis units that are going to be totally at extremes. The dialysis unit that has only the nursing home populations, it's going to have a very low fistula rate, whereas those that have the young people may have a fantastic fistula rate. So what are you going to do with the information then? Spank the older one?

DR. ANDRESS: I think our intention is that we developed the measure so that it can capture more appropriately some of these issues that have been raised with regard to facilities that are treating patients who may not be appropriate for fistula use while still recognizing that the predominance of the evidence would suggest that fistula usage is appropriate for most patients. And so that's why we had the genesis of the risk adjustment put in place.

So the adjustment is really designed, as John noted, to account for variation that results from patient characteristics along those

lines. So if you have a facility that treats a lot of patients that are captured within the risk adjustment, then the risk adjustment will account for the facility's performance that is a result of those -- the patients' characteristics.

MEMBER GREENSTEIN: But then shouldn't you put in all the exclusions, the additional ones that we mentioned? The patients that you know you cannot create a fistula so that one should be excluded. The IV drug abusers that you know that has very poor veins, therefore that should be excluded also? Otherwise, you're going to -- units will be at extremes again.

DR. ANDRESS: So I think we've discussed this to some extent. I think the point to be made is that we're not -- we aren't able to capture some of the information that's been discussed, so we were talking -- we were all talking previously about patients who have exhausted all vascular access options. We don't necessarily have the data to be able to capture that.

I think from a policy perspective, we still think that addressing vascular access is a sufficient quality issue that we are comfortable moving forward with the measures that we've presented here and that they, in fact, give us the opportunity to grapple with that information in the future and that that can be addressed through future measure maintenance as the measures mature and as the data mature.

DR. SEGAL: And if I can just add that some of the -- at the extremes, some facilities' fistula rates change by up to 10 percent. So if your fistula rate goes up by -- your standardized fistula rate goes up by 10 percent, that sends a pretty strong signal that your patient population is very different than the national average that we're adjusting to.

MEMBER KLIGER: I guess the one last thing, again, as a modest concern I have, but still is nagging at me is that we've never analyzed patients by their choice.

So if you take the 85-year-old woman

who has been through three procedures before, who says doctor, I just don't want to have another operation, I don't know that we've used -- in the multiple factors we have to consider for case mix adjustment, we haven't talked about patient choice. So I just think that's important to recognize.

The other thing is that the unintended consequences always can be patients being coerced or patients in subgroups that may not have a substantial advantage with a fistula being coerced into getting that operation or series of operations when we don't have evidence in that subgroup that it is helpful, for example, the frail elderly.

And I understand you have the case mix adjustment to look at it, I just think it's important to remember that there can be unintended consequences at the sharp end -- at the front end as we take care of those patients.

MEMBER HARTWELL: This is Lori Hartwell. I just want to make a comment just

because it came up at the last meeting, but a few of our members are having trouble finding a skilled surgeon and they've had some bad experiences with fistula placement, so I don't know if that's making -- I'm sure it's -- you know making their decision for them, I don't want to have another fistula incision. I've had a bad experience. I'm going to keep a catheter.

MEMBER KLIGER: So just the last for me, just personally having considered all of those issues in usability and use, I still personally think that this is very usable and of substantial use.

CO-CHAIR CROOKS: Not to make the perfect the enemy of the good in a sense, right? Okay. Are we ready then to vote on use and usability? Let's do that.

MS. OGUNGBEMI: We are now voting on usability and use for measure 2977. Your options are 1, high; 2, moderate; 3, low; and 4, insufficient. Voting is now open.

(Voting.)

MS. OGUNGBEMI: Results are 37 percent high; 63 percent moderate; 0 percent low; and 0 percent insufficient. Measure 2977 passes on usability and use.

CO-CHAIR CROOKS: Thank you, committee. We're moving along on agenda or -- I'm sorry, let's do an overall vote. Thank you. And then we'll do the public comments and then maybe lunch. Okay. Just to motivate. Okay, please go ahead.

MS. OGUNGBEMI: We are now voting on the overall suitability for endorsement for measure 2977. Your options are 1, yes; and 2, no. Voting is open.

(Voting.)

MS. OGUNGBEMI: Results are 100 percent yes, 0 percent no. Measure 2977 passes on its recommendation for endorsement.

CO-CHAIR CROOKS: So that's why I was saying, why vote, you know?

Okay. Thank you very much. So let's do our -- let's hear from the public now. We

have -- we can open up the line for now.

MR. LYZENGA: Operator, can you open the lines for public comment.

OPERATOR: Yes, sir. At this time if you'd like to make a comment please press star and the number 1.

(Pause.)

OPERATOR: There are no public comments at this time.

MR. LYZENGA: Do we have any comments from the back of the room?

MEMBER MADDUX: Since I had to recuse myself, I have to make a public comment. I would just like the measure developers to think a little bit. Their variety of stem cell derived and other kinds of vascular material that's coming to the fore that may be difficult to classify between fistula and a graft. And I think it would be wise to begin to think about how to categorize these as we move forward.

Not directly related to -- well, related to this measure, not in the next year,

probably, but as this measure gets itself into play, these hybrid devices might well be available.

CO-CHAIR CROOKS: All right, if there's no more public comments or recused committee member comments, we'll break for lunch and reconvene at what time? Approximately 12:30. Okay. Thank you.

(Whereupon, the above-entitled matter went off the record at 11:52 a.m. and resumed at 12:16 p.m.)

CO-CHAIR ANDERSON: So, are we ready for discussion of Measure 2978, the Hemodialysis Vascular Access Long-Term Catheter Rate? And that is Fred, Myra, and Michael Somers.

Who would like to go? Okay, thanks.

MEMBER SOMERS: So, this is Measure 2978 looking at long-term catheter rates. It is an intermediate clinical outcome measure, facility-level.

In the rationale, we are told that, among prevalent maintenance hemo patients in the

U.S., catheter use has declined from 28 percent to 18 percent from 2016 until the summer of 2015. Yet, the percentage of patients using catheters for more than three months has not shown a similar decline, only going down by about a point from 12 percent to 10.8 percent.

The numerator of the measure is the number of adult patient-months in the denominator on maintenance hemodialysis using a catheter for more than three months or equal to three months as of the last hemodialysis session of the month. And the denominator is patients greater than or equal to 18 years of age on the first day of the month on maintenance in center or home HD.

Exclusions to the denominator include pediatric patients, PD patients, less than a month at facility, and similar to the last measure we discussed, having a limited life expectancy in terms of being in hospice, metastatic cancer, end-stage liver disease or coma, hypoxic brain injury in the last 12 months.

Moving on to evidence, there are 12

studies that are initially presented spanning between 1991 and 2004. Most of those are retrospective and observational, looking at whole groups and not necessarily subpopulations. And then, there is updated with 13 more recent reports in the literature. Seven of those are reviews or systematic reviews; three are opinion pieces; two are observational retrospective presentations, and one is a decision analysis.

Again, I think similar to our discussion for the last measure, when you look at the evidence, although the most compelling evidence is retrospective and observational, overall, my opinion of the evidence was that it met the moderate criteria.

Anyone have any other questions, discussion points on that?

(No response.)

CO-CHAIR CROOKS: Shall we go ahead, then, and vote on evidence at this point? Everybody ready?

MS. OGUNGBEMI: We are now voting for

Measure 2978, evidence, Hemodialysis Vascular Access Long-term Catheter Rate. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. Voting is open.

(Voting.)

MS. BAL: Lori, have you rejoined the call?

(No response.)

I don't think she has rejoined. So, we will stop it here.

MS. OGUNGBEMI: So, having 18 votes, our results are 22 percent high, 78 percent moderate, zero percent low, and zero percent insufficient. Measure 2978 passes on evidence.

CO-CHAIR CROOKS: So, we broke the protocol a little bit, I guess. You are sitting here waiting to speak, and we just went right past. So, I would like to pause now.

(Laughter.)

I think maybe it is best not to say anything.

(Laughter.)

But I would like to pause now, give you a chance to tell us why you developed this and any other information you would like to share.

DR. SEGAL: Actually, I'm okay waiving my right to an opening statement.

(Laughter.)

No, I appreciate the opportunity. Really, much of what we have discussed, obviously, in the prior measure applies to this one, including my introductory comments.

I am happy to highlight a couple of the differences between the catheter measure that the group is considering today versus the currently-endorsed one, and I will just leave it at that. And they are actually the same similarities as to the prior measure.

So, similar to the fistula measure, again, this measure applies to all eligible hemodialysis patients, not just Medicare beneficiaries, again, using CROWNWeb as our datasource.

The second main point is that patients using a catheter, even if combined with a fistular graft, are now counted in the numerator of this measure. So, it is similar in the last measure in the denominator; now in this measure it is in the numerator. And that is different than the currently-endorsed measure. And then, the exclusion criteria which we have discussed are also being applied here.

So, thank you.

CO-CHAIR CROOKS: All right. Discussion of the performance gap.

MEMBER SOMERS: Okay, for the gap, we are provided with information from CROWNWeb as of 2014. It shows a range of patients in units with catheters going from zero percent to 58 percent, with a median of 10.5 percent interquartile, from 7 percent to 14.9 percent, and a mean of 11.6 percent. So, it does look as if there is this population who continues to have catheters. And as I alluded to at the beginning, the number of patients still with catheters for more than three

months has not declined by much over the last decade.

There is also some disparities data that is given to us that shows that women are 55 percent more likely to have catheters. Older patients of greater than 75 years of age or younger patients less than 25 years of age are more likely to have long-term catheters. Whites are less likely to have a catheter. Patients who have had end-stage disease for less than one year are more likely to have a catheter or who have had end-stage disease for more than nine years are more likely to have a catheter.

So, again, I thought this data did demonstrate that there was a gap.

MEMBER GREENSTEIN: Do you guys have any explanation for why the 18-25-year-olds have a higher catheter rate? That doesn't make sense.

DR. SEGAL: I don't have specifics other than to tell you that it is a relatively small group, obviously, of young patients. And so, the question is, are these people who are

dialysis and have catheter in transition to transplant as short-term or reasons along those lines? But we don't have specific reasons for why that group stands out.

MEMBER KLEINPETER: But do you have any data on their IV drug use because that is the population of our patients that are IV drug users, the 18-to-25? Can you pull that data --

DR. SEGAL: Actually, that is a great question. We have not done that analysis, but that would be relatively straightforward for us to do, is to look at the interaction between age and IV drug use and see if that is one of the things that is driving that.

MEMBER KLEINPETER: Okay.

DR. SEGAL: Thank you.

MEMBER GREENSTEIN: Yes, but those patients should have grafts done. They shouldn't have catheters and, then, they should have a lower catheter rate because a graft can be put in.

MEMBER KLEINPETER: Just anecdotally,

our surgeons won't operate on them if they have had any bloodstream infections and they are actively using drugs.

MEMBER GREENSTEIN: Well, the catheter is just going to be now you are just giving them easy access to shoot up the drugs.

CO-CHAIR CROOKS: Okay. Other comments about performance gap? Is there one?

(No response.)

Shall we vote?

MS. OGUNGBEMI: We are now voting on the performance gap for Measure 2978. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. Voting is open.

(Voting.)

Results are 22 percent high, 78 percent moderate, zero percent low, and zero percent insufficient. Measure 2978 passes on performance gap.

CO-CHAIR CROOKS: Okay. Please proceed, Michael.

MEMBER SOMERS: All right. Now on

reliability, in terms of specifications, I think that the same discussion that we had for the last measure could apply to this as well. So, I won't belabor that point.

In terms of reliability testing, it was done for centers that had at least 11 patients the entire year and showed IUR of 76.5 percent. So, fairly high IUR for the IURs we have been seeing.

CO-CHAIR CROOKS: Okay. Other comments on reliability?

(No response.)

And again, specifications I guess are tying into -- does somebody have their card up? Oh, Lorien? Sorry.

MEMBER DALRYMPLE: I just had one question on the specifications. My understanding is that other unknown and missing fields are counted as catheter, which may be an appropriate assumption. But I was wondering if we could just get clarity as to why those two are being counted in the catheter numerator.

DR. SEGAL: We include those as a catheter -- first of all, the number of unknown and missing is very small. So, this is not particularly impactful. But we wanted to make sure that, to possibly prevent gaming the system if you didn't report your access, we wanted there to be a strong incentive to know that, if you weren't reporting your access, you were going to be counted as catheter and that should be motivation to make sure you are up-to-date.

CO-CHAIR CROOKS: Okay. Other comments?

(No response.)

Okay. Let's vote on reliability then.

MS. OGUNGBEMI: We are now voting on reliability for Measure 2978. Options are 1, high; 2, moderate; 3, low, and 4, insufficient. The voting is open.

(Voting.)

One of our Committee members stepped out. So, we are now down to 17 votes, but the results are, for reliability, 47 percent high, 47

percent moderate, 6 percent low, and zero percent insufficient. Measure 2978 passes on reliability.

MEMBER SOMERS: So, for validity, there was a regression model done to measure your facility quintile level versus the SMR and the SHR, and we are given data that shows the relationship is as one would hope to see with higher levels of mortality and hospitalization with catheter use.

We are also given some data in terms of exclusions, and it is similar to the last measure with only a very small number of patients seeming to be excluded from this with 2.35 percent of the patients with no risk adjustment performed.

CO-CHAIR CROOKS: Okay. We are open for more comments on validity.

Well, Lorien?

MEMBER DALRYMPLE: There are only two areas that I thought it would be helpful to get the Committee's perspective on. One, there were

major differences shown with respect to vintage in terms of one of the largest risks of having a catheter were being incident to dialysis.

And then, also, I thought there were differences shown with respect to type of insurance, which I think is important, particularly in certain regions where your insurance type dictates whether you have access to a vascular surgeon in a timely fashion. Even within 90 days, does it happen in some regions?

So, since this metric is not risk-standardized or adjusted, I thought we should discuss that as a Committee. And I know the developers put forth arguments as to why not risk adjust, but I do have concerns that not taking into consideration things like vintage or insurance coverage don't really account for very substantive differences between certain facilities in any given area.

CO-CHAIR CROOKS: So, are you arguing for an adjustment for insurance type?

MEMBER DALRYMPLE: I think it is worth

discussing whether vintage and type of insurance should be accounted for when examining catheter rates at the facility level because the vintage data, I thought, was some of the most impressive presented. And then, I need to find the page with the medical coverage.

But, at least in my region, that is probably one of the most important determinants as to whether you will get timely vascular access, is what type of insurance you have and whether you are capitated to a group that can actually provide that service, and the wait list is quite long.

CO-CHAIR CROOKS: I would argue the opposite, though, that that is why it should not be adjusted away. If I am a facility and I have a low result and that is because the insurance my patients have isn't covering them adequately, then that is my job to go back and tell this insurance company, "Hey, you're killing my rate here. How come up you're not able to get me a vascular surgeon?" You know, it is an

opportunity for improvement that you need to take. I wouldn't want to see somebody getting a break for that.

MEMBER DALRYMPLE: So, you feel like the facilities can negotiate with Medicaid, for example, to get access to care, is the argument?

CO-CHAIR CROOKS: More or less, yes. And you have an argument to make to the payers that if they get these patients vascular access upstream or sooner, as soon as they get on dialysis, you are going to decrease mortality, decrease hospitalizations, and decrease their costs. So, you have ammunition to go talk to them.

So, yes, there may be others in the healthcare system that should be having that conversation, too, but you, as a nephrologist or medical director, I think you have an obligation to go back to the insurers and say, "Listen, you're not paying for the service that these patients need."

The vintage may be explained by the

fact that there are running out of vascular access sites. Is that your question, whether long-term patients --

MEMBER DALRYMPLE: The most profound effect was in those less than one, but it was also seen in those greater than nine. But I think the odds ratio approached four for incident patients. And at least my understanding is some facilities are denying placement for patients with catheters. And so, there are real unintended consequences, I think, potentially if decisions about facility acceptance is based on whether you have a catheter.

CO-CHAIR ANDERSON: Myra, did you have a comment?

MEMBER KLEINPETER: So, is it possible to the developer to be able to tease out that information about insurance status, simply because in this era where a lot of the commercial entities that have participated in the Affordable Care Act are pulling out of the system, this is only going to be a bigger problem moving forward,

with a lot of people in that first 90-day period not having adequate coverage to be able to get the vascular access. I know in Louisiana in that first 90 days it is next to impossible to get a permanent access in the patient.

DR. SEGAL: I will just say that we specifically asked the TEP about risk-adjusting the catheter measuring, including for things like vintage and whatnot, and the decision from the TEP was not to risk-adjust this measure, out of concern that it may be too likely to give facilities a pass on issues that may be in their control. Now I realize vintage is not one of the things in the facilities control, and insurance status, clearly, is a tough one to handle, but it may be possible.

MEMBER WAGNER: I would echo some of those comments. No insurance is, of course, not, then, something that one can influence a payer regarding, and that is a real issue in some areas.

And I think that another part of this

is one would like in some patients to have the opportunity to use particular surgeons, given their skill set. It would be, I think, not in the patients' interest to refer patients simply to someone who is in the network that happens to be covered by the insurance if that is not the person that can potentially do the best surgery for that patient.

CO-CHAIR CROOKS: Okay. Other comments on reliability? I'm sorry, on validity of the measure?

(No response.)

Are we ready to vote?

Seeing no dissent, let's vote.

MS. OGUNGBEMI: We are now voting on validity for Measure 2978. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient, and we are now back up to 18 votes because our Committee member on the phone has rejoined us. The voting is open.

(Voting.)

The results are 17 percent high, 72

percent moderate, 11 percent low, and zero percent insufficient. Measure 2978 passes on validity.

CO-CHAIR ANDERSON: Okay. Moving right along, Michael?

MEMBER SOMERS: For feasibility, again, this is exactly similar to the discussion we had for the last measure in terms of collecting the data and the fact that most of this is already collected.

CO-CHAIR ANDERSON: Any questions for the developer or further comments?

(No response.)

Are we ready to vote? So, we are voting on feasibility.

MS. OGUNGBEMI: We are now voting on feasibility for Measure 2978. Options are 1, high; 2, moderate; 3, low, and 4, insufficient. The voting is open.

(Voting.)

The results are 78 percent high, 22 percent moderate, zero percent low, and zero

percent insufficient. Measure 2978 passes on feasibility.

CO-CHAIR ANDERSON: All right. We're moving on to usability and use. Michael?

MEMBER SOMERS: In terms of usability, as the measure steward has told us, they are hoping to plan to use this measure along with the other measure for planned use and QIP for DFC.

In terms of the comments that we got from other members of the Committee, most of them thought that this would be very usable and there was only one comment about concerns about a subset of the population for whom the catheter is not a good choice, and they had some qualms about the measure in that. But, again, we have addressed that as, hopefully, being a small proportion of most centers' population.

CO-CHAIR ANDERSON: Any questions for the developer or further comments?

(No response.)

We are ready for the vote for use and usability.

MS. OGUNGBEMI: We are now voting on usability and use for Measure 2978. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. The voting is open.

(Voting.)

The results are 56 percent high, 44 percent moderate, zero percent low, and zero percent insufficient. Measure 2978 passes on usability and use.

CO-CHAIR CROOKS: So, let's vote on the measure overall.

MS. OGUNGBEMI: We are now voting on 2978's overall suitability for endorsement. Options are yes, 1; no, 2. The voting is open.

(Voting.)

MS. BAL: Lori, we are still waiting for your vote. Please send it in.

(Voting.)

We received it. Thank you.

MS. OGUNGBEMI: The results are 100 percent yes and zero percent no. Measure 2978 is recommended for endorsement.

CO-CHAIR CROOKS: Okay. We're halfway done. Well, not quite because we do have the opportunity today to look at the medication reconciliation measures, you probably read in your email, but that comes later.

We don't need a break yet, and we had decided that we would defer the discussion on harmonization and competing measures on the vascular access measures until the post-meeting phone call in about a week.

So, that being the case, we could move right to Measure 2979, the Standardized Transfusion Ratio.

CO-CHAIR ANDERSON: It is Michael, Lisa, and Jess. I think Jess is out of the room.

MEMBER LATTS: Michael is going to take the lead.

CO-CHAIR ANDERSON: Oh, okay.

CO-CHAIR CROOKS: So, first of all, Joe?

DR. MESSANA: Yes. Good afternoon.

I want to preface this by saying this

is not a vascular access measure and I'm not John Segal. So, for those of you who remember our fun meeting last year, we had a lot of enjoyment with a measure that was almost identical to this. I anticipate a lot more fun.

I'm Joe Messana, a clinical nephrologist at the University of Michigan.

Doug, do you want to introduce yourself?

DR. SCHAUBEL: Yes. I'm Doug Schaubel from the Biostatistics Department at the University of Michigan.

DR. MESSANA: Doug did the heavy lifting on the statistical analyses underlying the model. This is an indirect standardization model. And so, it is a ratio, not a rate, because of relatively infrequent events, just to clarify from the earlier vascular access discussion.

So, just a couple of opening comments that I think generally echo the comments I made last year. First, one point of clarification.

There was really an extensive discussion last year before we actually started talking about the merits and limitations of a very similar measure last year about whether it was an outcome, the health outcome, or an intermediate outcome.

I want to clarify there was an agreement to move forward assuming it was a health outcome last year. When I prepared the revised submission forms this year, after looking at the NQF criteria and knowing what the results of that discussion were, I submitted this as a health outcome, based on that discussion and moving forward. We haven't gotten any pushback until today about that decision. And so, I would humbly suggest that this measure be considered as a health outcome based on those criteria and last year's discussion.

Andrew, I don't know if you have anything to add about that opinion.

MR. LYZENGA: The only thing I would say is that we would affirm that this measure does fall within the bounds of an outcome measure

under NQS definitions, which does say in some situations resource use, which I think this could be considered resource use, may be considered a proxy for a health state. For example, hospitalization may represent deterioration of health status. We do think this falls within reasonable bounds of that definition as NQF represents it.

CO-CHAIR CROOKS: May I just comment on that, the proposition, too?

DR. MESSANA: Sure.

CO-CHAIR CROOKS: Outcome measures such as mortality or hospitalization, you say that outcome is a bad thing. A transfusion is not necessarily a bad thing. Is there any way to set -- does the measure give us a target or give us this is the best outcome?

DR. MESSANA: If you are asking me specifically, I have actually had people argue within the last six months or a year in the context of the CECI that mortality wasn't necessarily a bad outcome and we don't capture

most of the good deaths that occur.

I think that is the issue with any outcome; it is going to be imperfect. Generally, most of the literature and the guidelines, not necessarily up in space, say that unavoidable transfusions are not optimal anemia management. There are situations where transfusions are lifesaving, but the question is whether those vary across providers, in particular. So, it is not an answerable question.

CO-CHAIR CROOKS: No outcome is always good or always bad.

DR. MESSANA: Right.

CO-CHAIR CROOKS: Alan?

MEMBER KLIGER: Andrew, can I ask your help again? Because I cannot get my head around this being defined as an outcome for patients. If I were a patient, whether I get transfused or not is a process of my care. It is not an outcome that I experience. So, can you help me understand how you define this as an outcome?

MR. LYZENGA: Again, we didn't define

it as an outcome; the developer did present it as an outcome. We determined that it is within the bounds of our definition of an outcome, which, again, the sort of closest analogy I could present is as a readmission measure. A readmission measure is in some sense a process. What it does is it marks, in some sense it serves as a proxy for deterioration in a patient's health status. The hospital in that case has not done a good enough job of managing their care after giving them discharge instructions, and it results in a readmission, which, again, in many cases is a positive thing. Some patients need to be readmitted.

In this case, the transfusion would serve as a marker that the patient's blood has not been managed effectively. But I would defer, again, to the developer to really explain their rationale in doing that.

DR. MESSANA: So, Alan, on the evidence form it talks about health outcomes and it says, "events that mark use of scarce

resources". So, I don't believe that using it as a proxy for general deterioration is an appropriate argument for a health outcome.

But the use of scarce resources or use of resources particularly where you are comparing an event to no events, even if it is relatively scarce events, in the NQF evidence forms they talk about that as an appropriate health outcome metric.

MEMBER KLIGER: So, that would be an outcome for the healthcare system, but not for the individual patient.

DR. MESSANA: Yes. Just like hospitalization.

MEMBER KLIGER: No, no, but the difference is hospitalization clearly is an outcome for an individual patient. Getting hospitalized is an event that patients would prefer not to have. It is a clear outcome that makes a difference to patients.

DR. MESSANA: Right.

MEMBER KLIGER: But getting a dialysis

treatment or a transfusion or a cardiac catheterization are not outcomes.

DR. MESSANA: Giving a transfusion that precludes access to kidney transplantation, or something like that, I think should be viewed as an outcome for a patient.

MEMBER LATTS: I would tend to agree that this would be considered an outcome in how we are thinking of outcomes in performance measurement. For example, the process is the act of measuring whether or not you had the test done. So, whether or not you had your hematocrit drawn, whether or not you had your A1C drawn -- whereas the outcome in diabetes care would be considered what your A1C number actually is. So, I would think that this would be a parallel. The process would be was your hematocrit checked; the outcome would be was your hematocrit low enough that you, then, needed a transfusion.

MEMBER KLIGER: Then, the hematocrit is the outcome, not the transfusion.

DR. MESSANA: Maybe I should make my

opening statement that attempts to associate or demonstrate that achieved hemoglobin or the process of anemia management by a dialysis facility, those are processes and intermediate outcomes or intermediate outcomes and processes, respectively, that are strongly associated with subsequent transfusion risks in this population.

MEMBER KLIGER: I would buy that, but the transfusion rate itself is a process. The intermediate outcome, indeed, would be the measures of adequacy of anemia management.

DR. MESSANA: So, I'm certainly not, based on the discussion from last year, and the fact that what argument you can make when you submit to NQF, I mean, I would beg for a little bit of consistency here. Last year we moved forward after this back and forth and talked about this as an outcome. I prepared this measure this year as an outcome measure, describing in the evidence links how the intermediate outcomes and processes related to the transfusion events. And I would just beg for

some consistency in how we define this moving forward.

CO-CHAIR CROOKS: Well, I hear what you are saying. You got the impression from this Committee within a year ago that, about a year ago, that this should be brought back or continued as an outcome measure. Now you're hearing some discussion about that.

One way to proceed would be to go through the process and, if someone on the Committee says, "I can't vote for this because it is not an outcome measure," that would be their change to vote no. I don't know, is that another suggestion how to --

MEMBER KLIGER: Yes, I am surely not going to stand in the way of this for sure. I mean, I might be in a small minority here.

CO-CHAIR ANDERSON: So, Frank, you had your --

MEMBER MADDUX: Yes, I have a question for Andrew, and it is just the question about whether an outcome has to be knowable by the

target responsible party. In this case, there are substantial questions about whether this outcome might even be knowable by the facilities as the object of the measure, as compared to hospitalization where the patient doesn't show up and where you can ask them when they come back. This is one that is a little tougher for me.

MR. LYZENGA: In the sense of whether or not a transfusion is an identified event?

MEMBER MADDUX: Whether today transfusion is an identifiable event by the target of the measure, which is the facility.

MR. LYZENGA: I think that would be something that would come up in a validity discussion most likely.

MEMBER MADDUX: Yes, I think feasibility.

MR. LYZENGA: Yes, but I don't know that it is necessarily applicable to this question of the type of measure it is. I think that would apply also to any kind of measure, a process or an intermediate outcome, whether the

definitions are precise and unambiguous enough and knowable, that they can be collected reliably and reflect on the performance of a facility or the accountable entity, if that makes sense.

MEMBER MADDUX: So, I guess the answer to the question would be that, for an outcome measure, there isn't a requirement that the accountable party necessarily know of the outcome?

MR. LYZENGA: I think, again, that may be something that would come up under validity, whether that is -- I don't know, I would ask, Sarah, do you have any thoughts on that?

MS. SAMPSEL: Yes, I mean, going back to your question, that is not how we have it defined as a requirement. I mean, it is an interesting question and it is something that comes into play, but that one is hard.

MR. LYZENGA: I'm sorry about that question.

MS. SAMPSEL: I'm sorry, what?

MEMBER LATTS: For hospitalization as

an outcome measure, the accountable party, you know, wouldn't necessarily know if someone was hospitalized somewhere else.

MEMBER MADDUX: Well, they would know; they don't show up. In this case, the patient is going to keep showing up. While I play the "not," something will have happened in between you could ask them about, and they might report that. But, just as likely, they might not recognize what you're asking or have some other mechanism to know.

And so, my question is about transfusion, but it is really more about whether an outcome measure has to be knowable by the accountable party.

MS. SAMPSEL: I don't think so.

The other thing I just wanted to mention, and Andrew has talked about this a little bit, where this whole interpretation of outcome versus process, intermediate outcome, it comes through the interpretation of the evidence criteria. The rest of the criteria, of course,

are going to vote the same.

So, really, what we would like to get from you before we go to any kind of a vote isn't an outcome or process, but is there evidence that supports the fact that, you know, the rationale for this measure that I guess reducing or assessing this ratio of the transfusion rate is linked to evidence of better outcomes.

CO-CHAIR CROOKS: Well, that is a bit different. If it is an outcome, then the evidence challenge is to show that there is a process that affects this outcome as opposed to sort of an opposite. It is not that this outcome affects something further down. It is what makes this outcome better, right?

MEMBER FISCHER: Can I make a suggestion? I mean, I think it would be nice to hear from the developer. So, myself and Lisa and Jessie reviewed this, and I had corresponded about this point via email with Andrew. I know I did, and I believe Lisa and Jessie did as well, that I evaluated the evidence, treating it as an

outcome measure, notwithstanding the concerns that everyone has nicely articulated.

And I think a lot of these points will come and we will get to the evidence. We'll have a discussion and, then, we will have a vote, just for the sake of kind of continuing to move forward.

CO-CHAIR CROOKS: Josh has been waiting for a while to make a comment.

MEMBER ZARITSKY: No, no, it is exactly what Michael said.

CO-CHAIR CROOKS: The same comment?

MEMBER ZARITSKY: I mean, I said, listen, if you want to consider it, I am fine considering this as an outcome. Let's just evaluate the evidence, then, based on an outcome and saying this is a surrogate marker for an outcome. If the evidence is not there, then we have got a problem. But we are just going to look at the evidence different than consider it a process as we did before, what Michael said.

CO-CHAIR CROOKS: All right. So,

would you continue then, please?

DR. MESSANA: Okay, great.

So, I am glad the opening comments have gone so smoothly.

(Laughter.)

The last point that I will make, just for the sake of time, there has been much discussion about variation in transfusion billing and documentation in Medicare claims both here and in public comments over the last year.

The fact is, at the dialysis facility level, this transfusion measure, the one that is being presented here, as compared to the one presented last year which uses somewhat different definition for a transfusion of that for Medicare claims, is pretty insensitive to changes in the definition of a transfusion of that, whether one excludes a certain subcategory of codes versus another.

Using objective criteria, about 95 percent of facilities have the same classification for their STRR under the two

alternative definitions of transfusion. That is the so-called more restrictive or conservative version presented here and the broader definition that was used last year.

For the 4 or 5 percent of facilities that change classification based on how the transfusion events were identified from claims, all the changes occurred across one category. So, nobody jumped from flagging as worse than expected to better than expected. All the changes were across one boundary. So, worse than expected, as expected, or as expected or worse.

And so, given the small impact of the definition of transfusion, that became a big discussion last year. I really believe that the important tradeoff that this group must consider is the potential negative consequences to dialysis patients associated with failure to endorse this measure versus the potential negative consequences of misclassifications for a minority of dialysis facilities.

That's all. Thank you.

MEMBER FISCHER: I am going to follow the script, first, just introducing the measure. I think it has been stated. And then, just the description, just so we are all on the same page.

This is an all-adult dialysis patients to ratio of the number of eligible blood cell transfusions observed in patients dialyzing at a facility to the number of eligible transfusion events that would be expected under a national norm after accounting for patient characteristics within each given facility.

Eligible transfusions are those that do not have any claims pertaining to the comorbidities, which we will get to later under the specifications. The idea is better quality is a lower score.

This is a facility-level measure. This was discussed last time. I will come up to some of the points of discussion. One of them we touched upon, whether it is an outcome measure, but I treated this as an outcome measure and as a new measure since it is here for the first time

and it has not been endorsed previously.

I think the first thing to drop down to, just kind of following the script, is to discuss evidence. One of the questions posed under outcome measures is, are there processes of care that can influence this outcome? And I felt that it was yes. Specifically, use of ESAs and IV iron are processes that affect this outcome.

In terms of the evidence itself, there were 25 citations of evidence that were provided. Much of it is derived from observational studies and much of it is derived about efficacy of ESAs and factors predictive of what leads to a transfusion.

In terms of kind of very robust evidence about transfusions and other more routinizable outcomes, a lot of that or the one important study I think that presented was looking at how transfusion leads to subsequent decreased rate of kidney transplantations and worse kidney transplant outcomes.

And there was one recent article

presented that showed a strong relationship between blood transfusions, PRA, and subsequent worst graft outcomes. Now there were other adverse effects with blood transfusion that were discussed, but there is not evidence for. But these include, and well-known to many people on the Committee, reactions, infections, compromising future vascular access, and cost. And those may not be a dispute, but I am just going -- those weren't supported by the 25 pieces of evidence.

The other, I think, study that was interesting was one that is in press by Maloney that looked at 400,000 hemodialysis patients between 2009 and 2012. What they did is they were trying to look at how changes in the bundle and safety around ESAs have impacted transfusion and how does that subsequently impact outcomes of care.

What they found, that at facilities that had greater dose reductions and smaller dose escalations, NESAs had lower hemoglobin values

and higher transfusion rates. I don't think there is any surprise there. Conversely, patients at facilities that had greater dose escalations and larger small dose reduction had higher hemoglobin levels and lower transfusion rates.

Importantly, there were no clinically-meaningful differences on all-cause or cause-specific hospitalization events across these groups. That varied by ESA use and subsequent transfusion use. And I only bring this up because, other than the kidney transplant, relating this to another recognizable outcome, there wasn't a lot of data for that.

I think the other source is always expert opinion. I think we have to take that, obviously, into account. And our own Dr. Kliger wrote a commentary on KDIGO in 2012. He spoke about there is a lack of research supporting optimal transfusion strategy for ESRD patients, and it is difficult to weigh the risks and benefits of red blood cell transfusion, I thought

was one of the pithy points from that opinion piece.

And then, the last thing I will say -- well, two more things and, then, I will be quiet -- there is a 2014 AJKD article that really reported a proof of concept at developing such a measure of standardized transfusions. I think they really made the point that this might be a more meaningful way of having a quality measure around the domain of anemia than what we have had before. And we will get into that later, about what was in the QIP and what isn't anymore.

And then, lastly, there was a Technical Expert Panel meeting hosted by the Arbor Research Collaborative for Health in 2012 that strongly recommended a measure such as this. I don't have any further details of the meeting or the details thereof, but that is the summary of the evidence as was presented in the application.

I don't know if the developer has anything further to add. And then, I will let

Jessie and Lisa, if they have any additional comments.

DR. MESSANA: The only addition -- I think that is a great summary; thank you, Dr. Fischer -- but the only addition, there was a patient-level retrospective observational study and, then, a facility-level similar-design study from the Chronic Disease Research Group in '13 and '14, I think, or it might have been '12 and '14, that are listed as well that show association of achieved hemoglobin in dialysis facilities predictive of subsequent transfusion risk.

So, that is all, but I agree with the summary.

MEMBER LATTS: The only thing I would add, and this may be better under the validity section, but I think it is very important that, as we are considering policy decisions on a global basis, that we consider measuring the implications of those changes. And so, I think that having the ability to measure those, the

implications of various policy decisions, is a critical feedback loop. We can argue about whether or not this is the perfect measure, but I think, conceptually, we need to be able to do that as it feeds into the evidence.

MEMBER HARTWELL: This is Lori Hartwell. I would just like to speak.

I think, too, that there may be some issues with this measure, but it is very important to patients. We don't have anything to measure anemia anymore in the country due to the lack of the FDA guidance. I think this is a real marker of anemia treatment in the country and if patients have to get a blood transfusion as a result of it.

With regard to the high antibody level, I mean, it is known to the people in the group that it is harder to get a transplant. Even UNOS recognized this by giving you extra points to go to the top of the list. So, therefore, I would just like the Committee to consider that.

CO-CHAIR ANDERSON: Alan?

MEMBER KLIGER: Michael, can I ask you and the others that did this more thorough review perhaps than some of us did of the evidence? It sounds from your description, and from my reading of this, that the evidence really is in two areas. One is in patients who are candidates for kidney transplantation, and the second is in patients who are on ESAs and where the ESAs are manipulated to either be less, or whatever, and the relationship to transfusions.

My question is, is that a correct interpretation? And the reason I ask your opinion about that is because this measure isn't particularly directed at specifically either of those subpopulations, but is directed against all patients.

MEMBER FISCHER: I think that, yes, I would agree. But, again, I think that there was expert opinion presented from a TEP and opinion pieces, expert opinion that they cited in journal articles. We have to weigh that as evidence, the

empirical evidence.

To me, the strongest was in regard to kidney-transplant-eligible patients. And just talking aloud, then one could think, is this something where you want to be targeting that subgroup where there is the most evidence? I think it is philosophical about kind of what level of evidence that one believes is needed to achieve that.

But, in terms of robustness, I found it most convincing in terms of negative downstream implications for a kidney transplant. I don't know, Lisa and Jessie, if you had a different impression.

MEMBER LATTS: I agree with that. The only thing I would add is that I think, even though small, the evidence of infection with transfusion is a real thing that doesn't necessarily need to be proved here.

MEMBER FISCHER: I think, again, that is why I say there is expert opinion and those things have been articulated along with other

concerns. I am presenting what was in the application, the data as is, summarizing it and trying to be in an unbiased fashion, but distill it down in a way that the pithy details I think are apparent to all to inform a voting decision.

CO-CHAIR ANDERSON: Josh? Who? Yes, Josh, yes. Oh, sorry. Okay. Ishir?

MEMBER BHAN: I guess I am still struck a little by this issue of what are the downstream effects. Certainly, I think the transplant effect is probably a real thing to consider, although, as pointed out, it may be not applicable to everyone.

And certainly there are concerns about infection, although those concerns may also be there with alternative treatments. So, iron, being aggressive about iron repletion may have similar effects; also, potential effects on the vasculature.

And then, as well, we know, and I think it has become increasingly recognized over the past few years, the effects of excess in ESA

use. So, I think we have to look at this in that context.

I think Peter pointed this out in the beginning. Are we sure that this is a bad outcome? You know, I think you could make arguments about good deaths and bad deaths and things. But, generally speaking, we would like to reduce the mortality. And I am not so sure that is quite so clear with regard to transfusion.

CO-CHAIR CROOKS: The other downstream effect that does affect the patient usually is cost. If we give the right amount of transfusions and not excessive, then I believe that is less expensive than giving ESA. And that may, in fact, be a motivation -- I don't know -- for CMS to develop this.

Alan?

MEMBER KLIGER: But, Peter, I would argue that you don't know what the right number of transfusions are. That is the flaw in that type of an argument.

CO-CHAIR CROOKS: Okay.

MEMBER FISCHER: The last thing I will just say, it is worth referring back to the algorithm that NQF has, right? And I think if we start in box one and we agree that this is a health outcome as submitted -- and I think there has been discussion now over the last 12 months about that -- then you move to box two. And really, that asks you simply, do you agree that the relationship between the measured health outcome and at least one healthcare action is identified and supported by this stated rationale? I mean, this is the algorithm NQF has. I guess, to me, the answer is yes, because there are clearly actions that we do, as I articulated earlier, that are obvious to all that impact this outcome.

Again, I reviewed this after conversations offline earlier with Andrew and others, that I believe this is an outcome measure as submitted.

MEMBER GREENSTEIN: I just want to

point one thing out. We are going to translate on sensitization. Probably what is happening now is that what is increasing sensitization rates is the fact that you have had a previous transplant more than blood transfusions. And that is really what is going on.

DR. MESSANA: So, Dr. Greenstein, I believe that is correct, although I think that the article that was referenced suggests that there is synergism between the other sensitizing events and blood transfusion.

And in response to the argument that we don't know what is the most effective anemia management therapy, I would argue that I know what fraction of patients on chronic dialysis in the United States are on EPO. The standard of care in this country is transfusion avoidance for the vast majority of our patients using EPO. It is in the package insert and we are all using it in the vast majority of our patients. For any individual patient, the risk/benefit is uncertain, I would agree, but I think the

standard of care is transfusion avoidance by use of ESAs and other appropriate agents.

CO-CHAIR CROOKS: Franklin was first.

MEMBER MADDUX: I just have a question, Joe, and I don't know the answer to this. There have been drastic changes in transfusion policies around cardiac surgery and other areas of medicine, hospital medicine, and so forth. What is the data with regard to what appropriate transfusion policies might there be for end-stage renal disease?

DR. MESSANA: I suspect you probably have an inkling about the answer, having written in that area as well. I have run across some of your blood-saving literature.

However, most transfusions occur in the inpatient setting, and I believe that the decisionmaking around most of those transfusion events is probably covered by the American Red Cross and other consensus organization statements, since most of these transfusion events occur in the hospital.

I think that a fair statement about consensus is that, if the hemoglobin is less than seven, there is very little argument about transfusing it. If it is between seven and ten, it is situational. If it is over ten, there is little or no justification for transfusion. That would be my brief summary of what I am able to find from Red Cross and international consensus statements. So, my guess is that ESRD patients fall under that rubric.

CO-CHAIR CROOKS: Josh? And then, I wanted to try to get to voting.

MEMBER ZARITSKY: Just briefly to reiterate, I mean, the problem I have, if we are going to use it as an outcome, and the evidence is that, as time has changed, we have to come to recognize that, sure, we wanted to avoid transfusions because we had EPOGEN. But now we have come to recognize that, like you said, EPOGEN carries a black box. These patients that we drive for very high hematic -- it is not necessarily the ones that can achieve it -- they

do worse. And so, the question is, where does transfusion play a role in these patients? And I don't think we have an answer.

We clearly see that transfusion can sensitize a patient, but I'm just not so certain about whether transfusion in the setting of patients who are resistant to EPO is a bad thing or a good thing. I don't know. That is where I am as far as looking at the evidence.

CO-CHAIR CROOKS: So, if we are to treat this as an outcome measure, then our vote is to the point of, is there anything in the process of care that will affect this outcome? And that seems pretty straightforward.

If we were to vote on it as a process measure, then all these other issues we have been talking about, that transfusing has negative outcomes or is against FDA, the black box warning or other things.

If it is an outcome measure, the task for the developer is to show that there is at least one process of care that affects this

outcome, and that's it. If it is a process measure or intermediate outcome, then the burden is to show that improving that process or improving that intermediate outcome affects health outcomes further down the line. If they could show both of that, then it doesn't matter maybe whether it is an outcome or process measure.

And I don't know that we are at that point, but we need to vote and we need to know why we are voting and what we are voting for, I think. So, I think we should vote on it as an outcome measure, and in that case the burden is that there is at least one process of care that can affect this outcome.

Any other discussion or would you like to put up a different rationale? No? Okay.

So, let's vote on it. Does it meet the evidence criteria as an outcome measure?

MS. OGUNGBEMI: We are now voting on Measure 2979, Standardized Transfusion Ratio for Dialysis Facilities. We are voting on evidence

for health outcome measure. Your options are 1, yes, and 2, no. Voting is open.

(Voting.)

The results are 90 percent yes and 10 percent no. Measure 2979 passes on evidence.

MEMBER FISCHER: I will just continue, then, to follow the script. The next part is opportunity for improvement. If you can, keep scrolling down.

What they have showed -- and this is shown in detail in the worksheet -- is data on performance gap across facilities. And this was based on CROWNWeb and Medicare claims data. As we will get into, the Medicare claims data is what is used to capture transfusion events, both inpatient and outpatient.

And they show standardized transfusion ratios, STRs, for 6,000 facilities from 2011 to 2014. And you can look that -- I mean, they present means with standard errors, and they also present it by percentiles. There isn't substantial changes over time, and there is a

large spread in the data -- that was my impression of that -- showing that there is quite a bit of variability. And it would seem to corroborate or suggest that there is a performance gap.

The one thing I would just say is, then, later on, when they talked about it -- and I don't want to go out of order, but I think this is relevant -- when they talk about the SCS, the sociodemographics, this I think has a little bit more maybe tangible clinical interpretation, where they, similar to the standard hospitalization ratio, the real question is that, using this STR which is based on a national average and, then, adjusted for case mix at a given facility, classifying facilities as better, no different, or worse than this national standard, and they calculated these scores like is done with SHRs using generalized estimating equations, which kind of gives you a sense as to how does that bear out in terms of significance.

And this is shown kind of much later

on in the worksheet. But I thought what was interesting is that this has a slightly different message, I would argue, than what we see kind of posted up there, in that, when all is said and done, 93 percent of the facilities come out to be as expected or better, which only 6 percent are worse.

And I think, then, again, this is philosophical, whether one views that still as a performance gap. I guess I want to be careful that this is not measure up for maintenance. So, this may not be as critical as a measure we are considering for re-endorsement. But I did want to bring it up, and if I have misinterpreted the data, the developers can correct me. But I thought it was important to talk about that just in terms of it looks like 6-7 percent of facilities are actually worse than what they would expect.

CO-CHAIR CROOKS: Yes, and while you are answering the question, could you just briefly explain where the better than expected,

as expected, and less than expected, how that is actually determined?

DR. MESSANA: Right. So, the flagging analyses are maybe drifting towards operational. The Efron empiric null approach with z-scores was used, so that we could control the flagging. So, it was actually set up with the anticipation that 5 percent of facilities expected would be on either tail.

So, it is kind of you can be as sensitive and lose specificity if you want. We set it up that way intentionally. I'm not sure it is appropriate critique necessarily to say that it can't be an impactful measure based on the relatively-strict criteria we used.

MEMBER LATTS: And the only thing I would add, then, is from a performance gap perspective, you know, again, given the changes in reimbursement, this would be one that you would necessarily would want to follow moving forward to see if the gap changed moving forward.

CO-CHAIR CROOKS: Okay. More

discussion about the performance gap?

MEMBER ZARITSKY: So, if I understand right, there is always going to be -- you set it up so that there is 5 percent -- there will always be 5 percent?

DR. MESSANA: I think that drifts into CMS policy decisions. We set it up to mirror standardized hospitalization using a similar technique, reasoning that a small fraction in either tail would be appropriate.

And how that might be used in a different program, right, is certainly beyond my ability to speak. It is set up for the purposes of consideration here with being relatively specific to extreme outlier facilities.

MEMBER KLIGER: So, I guess, Josh, it gets back to my basic concern, that there is ever a distribution, there are surely going to be outliers. By definition, we have set it up. And if we imply that that means that on one or the other end that people are getting inappropriate care, I don't see the evidence that that is the

case here. And so, when you look for performance gap, I find it hard to separate that decision from the underlying issue around transfusion.

CO-CHAIR CROOKS: Okay. Other comments on the performance gap?

(No response.)

Okay. I think we are ready to vote on that.

MS. OGUNGBEMI: We are now voting on performance gap for Measure 2979. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. Voting is open.

(Voting.)

We're waiting on one more vote. Could everyone just please vote one more time? Thank you.

(Voting.)

Results are in, and on performance gap we have results of 10 percent high, 60 percent moderate, 25 percent low, and 5 percent insufficient. Measure 2979 passes on performance gap.

CO-CHAIR CROOKS: Okay. The next issue is reliability and specifications.

Yes, Michael.

MEMBER FISCHER: So, let me just kind of go back through the numerator. Again, it is a number of eligible observed RBC transfusion events. And this is both capturing inpatient and outpatient transfusion events.

The denominator -- and I won't reread the whole thing -- but denominator was number of eligible red blood cell transfusion events at the expected facility given the patient mix. The exclusions, which I don't think we have talked about, now I think is the opportunity to do that -- we can do that here; I think it also has relevance to validity -- include transplant hospitalizations, cancer, bone marrow problems, and sick cell disease within one year of observation.

And they go into some detail about why they look back one year. They performed a logistic regression model demonstrating -- and

they didn't put the results, but they just kind of made a statement, which I assume summarizes their findings, that when they looked back longer periods of time, it didn't substantially lead to a different set of exclusions. So, I think that is why they are doing one year.

They also provide a detailed figure giving a case example. I think it nicely looks at how, when the exclusion is captured and, then, how it would be a forbidding period for one year. I think it illustrates, because I think it is a little bit hard sometimes to envision, when you are thinking of exclusions during a time period, but it nicely, I think, kind of characterizes how that would be done.

The data sources I think, because it gets into some of this, they plan to use for transfusion events -- this comes from Medicare claims ICD-9 and Value Center codes. Outpatient, they are HCPCS and Revenue Center codes and, then, CROWNWeb data for a lot of the other elements that we require to calculate it.

I thought the data elements were clearly-defined. The codes were provided. I thought things seemed logical and clear.

One thing that I think is always interesting is in terms of the things that go into the expected value calculation. I think it is kind of the customary covariates that they use for SHR ranging from calendar year to diabetes to age. I think we can take that as we have for other measures that have been endorsed.

The one thing that I did have a concern was, just kind of hypothetically thinking, what about individuals -- and I am now thinking about inpatients -- who have trauma or some unexpected surgery, blood loss, require transfusions? And that, you know, if you are thinking about this measure, unless I have a misunderstanding, that is not covered by exclusions. That would be a negative attribution to a facility in terms of the way the measure is interpreted.

That was the one thing that, you know,

just how often does that happen, I don't know, but I think it is one of those things where, really, is that a reflection of quality of care at the dialysis facility when people have acute hospitalizations for non-dialysis-related reasons that entail acute blood loss requiring emergent transfusion?

I don't know if the developer has a response. Or maybe I have misunderstood perhaps, but that was one concern; there may be others that Lisa or Jessie have about specifications.

DR. MESSANA: Thank you.

Michael, I think it is reasonable. We presented this measure last year, unsuccessfully, as being one in which there is shared attribution for events. And I will provide one single anecdote to describe what the literature says, and some of that literature is in the 25 articles that we have cited in the linking evidence.

I recently had a patient admitted to the hospital for urgent four vessel coronary artery bypass grafting. Diabetes was his cause

of end-stage renal disease. His hemoglobin at his last visit with me was about 11.2 or 11.3 grams per deciliter before his admission to the hospital. His post-operative hemoglobin nadired at 7.2. Clearly, he had blood loss as a consequence of surgery and potentially volume overload, dilution, and whatnot, post-operatively.

Had he entered the hospital, all other events being the same, had he entered the hospital with a hemoglobin of 9, both the literature says and my clinical experience says he would have gotten blood transfusion. Now was the dialysis management the sole cause of the potential exposure to ELO transfusion? No. But we considered this a shared risk kind of proposition, and that is explicitly what the TEP discussed when we were developing the measure in 2012 under their guidance.

MEMBER FISCHER: I guess, I don't know, maybe I shouldn't be drawing a distinction, but I understand that. It is a good example.

But I am thinking of something that directly contributes. I mean, if someone comes in with acute GI bleed or some traumatic accident, it is a little bit more difficult for me, again, just thinking about how that, since that is going to very linearly lead to a transfusion event. And frankly, it could be independent of where your hemoglobin was to start with, given the linearity with that impact and hemoglobin, but maybe I am splitting hairs as to how that would be saying that is reasonable to include.

CO-CHAIR CROOKS: Lorien?

MEMBER DALRYMPLE: I actually agree and made notes with similar -- it does seem like there are certain events that should be excluded such as acute GI bleed requiring hospitalization when it is the principal diagnosis and our patients are at heightened risk for GI bleed. Even with old heparin, there's a number of factors that contribute to it.

Another one I thought would be reasonable to consider but much rarer, to be

honest, so not quite as important, are things like polytrauma. Clearly, there are situations where your dialysis facility care will have minimal impact on whether you get transfused in that setting.

But GI bleed, have you all looked at this at all? Is it as frequent as we are worried about or perhaps you examine this in sensitivity analyses and it doesn't really play out as being terribly relevant?

DR. MESSANA: I will I could say that the latter was true, but most of the work that we have done related to the prospective payment system and looking at cost of EPO and recent GI bleed is associated with increased EPO use and, presumptively, greater risk for blood loss and transfusion.

The reason it is specifically excluded here is the TEP did not agree with you, basically. The TEP believed that GI bleeding was potentially influenceable, could be the result of care by the dialysis facility in some situations,

and they did not want that included in the list, and we stayed true to their recommendations.

CO-CHAIR ANDERSON: John?

MEMBER WAGNER: I just want to echo the comments about GI bleeding. In my own experience, that has been a problematic area for care of our patients, not only acute, but patients with recurrent GI bleeding, despite what we considered to be optimal management, as well as patients with inflammatory conditions, autoimmune disorders, sometimes requiring ongoing glucocorticoid therapy, associated at the same time with other blood-loss anemia. So, we had gynecological sources of blood loss as well as GI sources of blood loss in such patients. Despite our attempts to manage them with ESAs, it was not sufficient.

CO-CHAIR ANDERSON: Frank?

MEMBER MADDUX: Yes, I am just wondering if your analyses were able to distinguish between patients that were out patients at the origin of the transfusion order

versus hospitalized at the transfusion order, to try to get a little bit at Lorien's question on is there an acute issue that occurred, knowing that most transfusions are happening in the hospital, but they may be happening in the outpatient department of the hospital or some other site that wasn't associated with an admission.

DR. MESSANA: Yes, I don't have the answer to that. I think it would be asking a lot of claims because there is this ascertainment bias, right? People get admitted because you are more likely to identify diagnoses that may have preceded hospitalization because the admission is often associated with reporting of a significant increased number of claims. So, I don't think I can provide an answer. We clearly can differentiate transfusion events that occur inpatient and outpatient, but the timing of when the clinical condition came up, using Medicare claims I think is limited.

Also, the hemoglobin values that we

have access to generally, because of the reporting, come from the prior month. And so, they may be late in the month; they may be early in the prior month, but they are from the prior month, relying on the dialysis providers to get those.

MEMBER SOMERS: I just wanted to clarify whether this measure is supposed to pertain to children. Because in the brief description of the measure, it talks about this being for adults, but children aren't excluded in the denominator.

My concern would be, since a minority of children have Medicare coverage, that the data we would get for children would not really be true in terms of reflecting transfusion ratios. It wouldn't necessarily penalize. It would be underestimating things because we wouldn't be able to gather that data for the inpatients in terms of transfusions that they may receive.

DR. MESSANA: Yes, so I am surprised you bring that up because my belief was that this

was an adult measure, that this was intended to be an adult measure. We have almost no data to identify transfusion events because of the relatively lower fraction of pediatric patients that are Medicare and the small numbers. So, I will have to go back and double-check that, but my recollection was this was intended as an adult measure.

CO-CHAIR ANDERSON: In your stage one model, there are age groups for zero to 14, which I think leads us to believe that children are being included in the model. And there is also a 15-to-24-year-old age group.

DR. MESSANA: So, as I say, the exact specifications that we are presenting, I will go back and double-check on those. And Doug may want to comment on the model, if you have the moment.

DR. SCHAUBEL: Yes, just to follow up on your comment about stage one versus stage two, since stage one is getting the regression coefficients, so the basis for the adjustment.

And the second part is calculating the numerator and denominator, which is done separately. So, the stage one could, in fact, include children. That wouldn't be a problem for stage two.

MEMBER GREENSTEIN: I guess the other thing should be these patients are many times vasculopaths and they are going to undergo bypass operations besides cardiac operations, and they are going to get transfusion many times because, you know, vascular surgeons like to give blood.

DR. MESSANA: I won't comment on the description of vascular surgeons' preferences.

(Laughter.)

However, again, our literature suggests that in the general hospitalized population and ICU population and in surgical population, one of the strongest predictors of perioperative transfusion is preoperative hemoglobin.

CO-CHAIR CROOKS: Lorien, your card is still up?

MEMBER DALRYMPLE: I do have a question for the developers regarding the numerator count, just for clarity, because this seems similar to me to last year's measure. So, I was hoping you could provide information as to whether it is or is not.

My understanding is, if a hospital submits bills with procedure codes, every transfusion counts, versus if a hospital submits claims using a value code, it is one event, meaning hospital A transfuses 10 units. And let's say that is over 10 days. That is 10 events attributed to that facility. Whereas, hospital B bills with a revenue code, again administers 10 units, but that gets counted as one. Is that an incorrect understanding of this? Can you clarify?

DR. MESSANA: Yes, it is a little bit off and, actually, when I reviewed the transcript of last year's discussion. So, let me just try to reclarify.

So, according to the Claims Processing

Manual and the Red Cross Billing Guidelines, what you need to report or submit for an inpatient transfusion event is a revenue code, right, which really relates to whether the blood was purchased or whether it was donated and, then, how the hospital bills for blood processing and things like that, and whether they can use the transfusion, the cost of the blood in their cost report. It is related to that, to the purchase of blood versus blood being donated.

So, that revenue code is supposed to be required. In addition, a procedure code or a value code, a designated procedure code, ICD-9 or now ICD-10 procedure code, designating what type of blood product or what type of product was actually transfused, cryoprecipitate, platelets, frozen red blood cells, packed red blood cells, whole blood, et cetera.

So, last year the metric that we presented included transfusion events that were only identified by the presence of a revenue code without a procedure code. And that turns out to

be about 34 percent, 35 percent, depending upon the year of potential transfusion events.

It also turns out that, based on your comments from last year, we went back and looked at regional variation, network, state-level variation, hospital-level variation. And there was really quite a variation across providers in terms of whether the majority of transfusion events were billed under just a revenue code or, I will say more appropriately, more consistent with the Medicare claims processing, which is revenue code and a procedure code. Okay?

You can also document by submitting just a value code, but that is a very small fraction. So, the vast majority of transfusion events are either procedure code, ICD-9 procedure code, now ICD-10 procedure code alone, or in combination with a revenue center code. And then, there are a minority, a sizable minority, that are just revenue center codes.

There is a lot of variability in just a revenue center code percentage across states.

For example, Rhode Island I think has 14 percent of transfusion events that are just revenue center code. Utah has 74 or 75 percent that are just revenue center code.

And so, we were concerned about that variability and billing, particularly in the context of the comments you all made last year about reliability. So, we looked at the more restrictive definition. And what is interesting is that there does not appear to be any association between state-level dialysis facility flagging, whether you use one or the other definition. And the two definitions are including those transfusion events that are identified solely by revenue center code or revenue code versus only including transfusion events that have both a revenue code and a procedure code or just a procedure code, which is also a very small percent or something like that.

So, that is the real focus of the definitional difference, Lorien, is really whether or not you accept revenue code alone as

sufficient evidence for a transfusion event. You see a lot of variability across regions and states based on that practice at the hospital level. It turns out, though, that the STRR is insensitive or pretty insensitive to which definition you use.

We chose to use the more restrictive version for presentation here because it gets rid of some of that regional billing variability concern. It also reduces the number of transfusion events we identify by about 34 percent. For me, that is a bigger concern than the regional variability.

MEMBER DALRYMPLE: But can I clarify that point about procedure codes versus value codes? Because my understanding from this sentence is we identify a transfusion event for each transfusion procedure code with a corresponding unique date listed on the inpatient claim; thus, allowing determination of multiple transfusion events on inpatient claims with multiple ICD-9 procedure codes. However -- the

"however" is my part -- for inpatient claims with value code 37, we count the single transfusion event.

So, when I read that, what it sounds like to me is, if a hospital chooses to use procedure codes, multiple events are coded, versus if they choose to use a value code, a single event is counted. So, at least my initial understanding of that, and similar guidance is provided for the outpatient, where they compare HCPCS to Revenue Center, which you guys describe in detail and how the counting works. So, my initial impression is still your claim type somehow determines your numerator count, but I suspect value codes are infrequent, so less than 5 percent.

DR. MESSANA: It's extremely infrequent, right. Well, it is about 1 percent, something like that.

MEMBER DALRYMPLE: Okay.

DR. MESSANA: So, in theory, you are correct. In practice, it is not impactful at

all.

MEMBER DALRYMPLE: Okay.

DR. MESSANA: The real issue is revenue versus procedure codes. In the outpatient setting, providers are instructed only to submit one claim per day, no matter how many transfusion events. And in the outpatient setting we are absolutely constrained by that claims processing regulation. So, in the outpatient event, it is correct; you present two different HCPCS for two different transfusion products, but one revenue code. We can only bill for one event on a day, but we are constrained by the regulations.

In the inpatient setting, if a patient receives a unit of whole blood and two units of frozen packed red blood cells, you can identify the differences by the ICD-9 procedure codes, and there is no restriction on submitting multiple transfusion claims per day in the inpatient setting. That is the difference between inpatient and outpatient.

CO-CHAIR CROOKS: Okay. I would like to try to move on to the reliability. That was just the specifications that we have been talking about so far.

MEMBER FISCHER: Yes. Right. No, I think this is a good discussion because we are touching upon some of the key issues. This was one of them from last year that I think was a bit contentious. So, it is good that everyone has an opportunity to air out their concerns and potential explanations.

So, the second part of what we are going to vote on with reliability is the reliability testing. They tested at the measure level only, not data elements, which is fine. And they used the interunit reliability measure, which has been used for several of the other ones we have reviewed here today.

Just to remind folks, this score can range, the IUR can range from zero to one, zero revealing that most of the variation of the measure, in this case the STR between facilities

is random noise. The closer you are to one, the more likely it is that it is a good characterization of interdifferences between facilities.

So, I think we can put up whatever we can, but they had kind of a nice box that looked at IURs from 2011 to 2014. They did it overall. And the first thing I will say is the trends over time, they were very stable. The overall value is around .65 or so, which most would consider to be moderate.

The only concern I had here -- and I think the developers point this out -- is that there is a consistent discrepancy between small, medium, and large facilities. And they broke them down based on less than 46, 47 to 78 patients, and over 79. And it nicely divided the overall 6,000 or so into three groups, about 17-16 hundred apiece.

And if you look, and we can just look at 2014 data, the IUR for small facilities was about 0.3; medium, 0.5, and, then, the largest

facilities was 0.78. The immediate interpretation would appear to be that the IUR seems to indicate a lot more noise with small facilities. That is probably not a big surprise, but I think since it informs our assessment of reliability, and there are no exclusions for small facilities that I'm aware of, I think it is important just to take that into consideration.

I don't know if Lisa or Jessie have any additional comments.

(No response.)

CO-CHAIR CROOKS: So, we will have to be deciding whether that makes the reliability unacceptable or not.

Are there other comments on reliability?

I'm sorry. Michael?

MEMBER SOMERS: I think that this would be more evidence for why children should be excluded from this measure, since most pediatric dialysis centers are quite small, since measure wouldn't be very reliable for that population.

MEMBER FISCHER: The one thing I was just going to say is just, again, sticking to kind of this script and our guidance from NQF, if you worked through the algorithm, I think it really comes down to box No. 6. Based on the testing presented, you have high certainty and confidence, moderate certainty or confidence, or low. And I think that that, obviously, is a matter of people's interpretation of the data presented.

For me, I think we should probably -- I had moderate certainty, but my bounds of moderate may be broader than others.

DR. MESSANA: So, just for clarification, our support people in the back are yelling at me no children, no children.

(Laughter.)

So, they can confirm that this is an adult-only measure.

CO-CHAIR CROOKS: Okay. Are we ready to vote on specifications?

Oh, I'm sorry, Lorien.

MEMBER DALRYMPLE: Can I ask a question of the Committee then, particularly for the main reviewers? My understanding is 1900 units fall into the small facility size, less than/equal to 46, and the IUR in that group is .30. And another 1900 fall into the medium-sized dialysis facility group, and the IUR for that group is 0.50.

So, could the main reviewers clarify for us? I know you gave us your opinion, Michael, on how you went through the board, but it is challenging for me with such a large number of facilities having IURs of .5 and .30 to know how to use the guidance.

And I don't know if the NQF staff can weigh in on this. Okay, they are shaking their head no.

So, I guess the Committee and the main reviewers are left to give us some guidance. You know, it would be one thing if it was 10 facilities, right? We would all move on.

MEMBER FISCHER: I bring this up

because I wanted this type of discussion to gather people's opinions. I am not dogmatic here.

The thing I tried to remind myself is how many of the measures that we vote on don't provide reliability by facility size. I mean, I am kind of six one way, half a dozen the other.

But the developers presented this data, which I thought was quite interesting. But, you know, if we only had seen the overall IUR of .6, there would be no discussion; we would be moving right along.

So, when you are giving additional details that aren't necessarily requested, and then, they raise the concerns -- no, I mean, I probably should stop talking. But, I mean, I think it leads to some cognitive dissonance about how to process and arrive at a conclusion. Anyway, kind of thinking along those lines.

CO-CHAIR CROOKS: Well put. Okay.

MEMBER DALRYMPLE: Can I ask the developers if the model at all accounts for

facility size or attempts to deal with this? I don't know if perhaps in the expected part this somehow gets handled. Can you guys help us with that?

DR. SCHAUBEL: Yes, and it does not. And that's something that you wouldn't want to do, because if you did that, you would be comparing facilities at the same size. And if there are systematic differences between large facilities and small facilities, you would be washing that away. So, no, it doesn't; no, you wouldn't want to.

DR. MESSANA: I will add that, if this measure is used in public reporting and things like that, there are limits in terms of what facilities would be reported on based on size, but that is at the extreme. That is certainly not the entire 1900 in the lowest tertile.

CO-CHAIR CROOKS: Shall we vote?

MS. OGUNGBEMI: We are now voting on reliability for Measure 2979. Your options are 1, high; 2, moderate; 3, low, and 4,

insufficient. Voting is open.

(Voting.)

The results are zero percent high, 75 percent moderate, 25 percent low, and zero percent insufficient. Measure 2979 passes on reliability.

CO-CHAIR CROOKS: Okay. Let's move on to validity.

MEMBER FISCHER: Okay. So, moving along kind along the script to validity, I think, you know, the specifications I think they come up both with reliability and validity. I think we have brought forth some concerns about specifications such as polytrauma, acute GI bleed. I won't revisit those now.

Moving on to testing for validity, they did this, again, at the score level only, which is fine. What they did is they looked at the associations with tertiles of the STR with SHR and SMR, which are currently-endorsed quality measures. And using Poisson models, they showed that STR tertiles were significantly associated

with both SMR and SHR, that the relative risk for death and hospitalization increased with higher tertiles of STRs, as that numerical value became greater.

The other thing I think we talk about with validity testing is face validity. And they also provided face validity, and there was a statement from the developers that six out of the six voting members of CMS's 2012 Technical Expert Panel voted to recommend the development of a facility-level standardized transfusion average.

When I read that, it is "recommended the development of," which is a little bit different than recommending this specific measure. But I don't want to parse words, but just being careful to make sure I had a proper interpretation of what was in the application.

I think the other thing, but maybe I want to pause here, that we will need to talk a little bit about is the SDS factor analysis. But I will stop, and I don't know if Lisa or Jessie or others have things to add.

MEMBER LATTS: No, I think you got my comments.

DR. MESSANA: Well, I would like to clarify accuracy of the information presented, if that is okay, Peter. So, the third tertile analysis that was performed I think is very important relative to our discussion of outcome.

So, we showed that if you looked at facility-achieved hemoglobin tertiles and their relationship with subsequent transfusion events, we showed statistically-significant dose-type effects relationship under the validation as well.

MEMBER FISCHER: So, then, I think the other thing is to talk about, right, the SDS factor analysis, correct?

Again, I think, Andrew, when we had our conversation, our meeting the other week, this was a trial period. There was analysis that was presented in great detail, and other factors that were looked into were things such as sex, race, Hispanic ethnicity, employment insurance,

and outcome -- and income. Excuse me.

And they have some very nice, detailed tables. Kind of just summarizing, there were certain factors like female sex, Hispanic ethnicity, employment that did appear to have an impact on this measure. But, in the end, as the developers characterize, a very small percentage of facilities would actually change categories. And the three categories I spoke about earlier, it was around 1.5 percent or so, and that was from same to worse, same to better. So, there were trends in either direction.

You know, I think they went on to say about -- and I think it is kind of a philosophical question -- about whether one makes additional adjustments for these factors. As I understood from the developer, they don't plan on doing that.

And they kind of went on to make, you know, they gave some explanation thereof, despite finding that some of these are significant as to why they chose not to do that. For example,

regarding employment insurance status, we believe the association between transfusion events and these factors represent disparities in access to care. And therefore, we do not believe that they are appropriate risk-adjusters for quality measures.

And they talked about some area-level measures as well that reflect socioeconomic disadvantage. The one thing they didn't comment on that I guess -- and maybe I overlooked it, and Jessie and Lisa can fill me in -- is I get that, but what about Hispanic ethnicity? Because that is something that I think -- you know, is that worth consideration in terms of being a case-mix adjuster or not? I don't know what Jessie and Lisa thought or others or the developer, additional comments.

CO-CHAIR CROOKS: So, as it stands, then, there is no adjustment for SDS built into the model right now? Correct?

MEMBER FISCHER: Correct. That's right.

CO-CHAIR CROOKS: Okay. Other discussion regarding the validity?

(No response.)

Okay. I guess we are ready to vote then.

I'm sorry. Lorien? Hold it up.

MEMBER DALRYMPLE: A question of either other Committee members or the developers, just to clarify the interpretation of the standardized transfusion ratio. So, when I was looking at the earlier data, it looks like raw rates of transfusions have come down since 2012 a little bit, but it kind of peaked in 2012. But the standardized transfusion ratios and the distributions did not look notably different to me over the years. Is that a correct interpretation or incorrect? And can you kind of help us understand why the rates are coming down, but the standardized transfusion ratios aren't obviously coming down? So that we know how to use it as a performance metric: am I getting better kind of issue?

DR. MESSANA: It is analogous to the SHR and SMR. They have year effects built into the model. So, unless you tied it back to some baseline year, the STR as developed is adjusted or normalized to the national mean, median. Mean or median are almost the same.

MEMBER DALRYMPLE: The expected are getting better.

DR. MESSANA: The expected for that year, yes.

MEMBER DALRYMPLE: So, the observed relative to the expected is staying? Okay.

MEMBER FISCHER: The only other question I had is I think in the SHR and SMR, claims data for Medicare is now used to update for prevalent comorbidities. After I reviewed this, I looked at those, which I was not primarily assigned to, but, then, I went back to this. And I was wondering why that also isn't true for this measure, why it wouldn't somewhere be feasible since things such as diabetes and others go into the determination of the expected

value. I just didn't know if the developers had a comment.

DR. MESSANA: So, the TEP for this metric was in 2012. The TEP for use of prevalent comorbidities was in 2015, and you will be talking about that later. The approach that was recommended by the 2012 TEP was to use exclusion as a risk-mediation approach as opposed to risk-adjusting for a bunch of different comorbidities.

The 2015 TEP was asked specific questions about whether prevalent comorbidities specifically with regard to hospitalization and mortality could be the result of facility practices. We don't have specific information about a Technical Expert Panel's opinions about how comorbidities could be the result of facility care that might influence the transfusion metric.

But our risk-abatement strategy excludes 15 to 20 percent of Medicare patients each year. So, we are using the all-or-none risk-abatement approach.

CO-CHAIR CROOKS: Okay. Any other

discussion?

(No response.)

Let's vote.

MS. OGUNGBEMI: We are now voting on validity for Measure 2979. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. Voting is open.

(Voting.)

Results are zero percent high, 75 percent moderate, 25 percent low, and zero percent insufficient. Measure 2979 has passed on validity.

MEMBER FISCHER: I think next up is feasibility.

CO-CHAIR CROOKS: Correct.

MEMBER FISCHER: I'll make this brief. I think it is very feasible. It is already in use as a CMS DFC measure. I don't have anything else to say.

CO-CHAIR CROOKS: More comments?

(No response.)

I think we can go ahead and vote on

feasibility.

MS. OGUNGBEMI: We are now voting on feasibility for Measure 2979. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. Voting is open.

(Voting.)

We are down to 19 votes because one of our Committee members stepped out. So, our results are 79 percent high, 21 percent moderate, zero percent low, and zero percent insufficient. Measure 2979 passes on feasibility.

MEMBER FISCHER: I think, then, second-to-last is usability and use. I think it is already in use as a DFC measure since 2014. It is approved for the QIP in payment year 2018.

Just kind of getting to the most important points, the one thing I think that also comes up in usability -- and we touched upon it briefly, but it is asked specifically here in this script -- is about unintended consequences. Specifically, and the developers acknowledge this, about is there a concern that higher

hemoglobins could be targeted, for some of the reasons why we have articulated up to this point in the conversation.

I think that they believe that that is less likely, given that oftentimes transfusion avoidance should be satisfactory with hemoglobins even over 10. So, no reason necessary to go over 12 or 13. That is the argument or the point I understand from what was documented.

What I just would point out, though, is that, previously, if I am correct, there was a QIP measure, right, for hemoglobins greater than 12, and that no longer is ongoing. And the new measure is just looking at, you report number of months of hemoglobin and ESA use. There is no hemoglobin cutoff.

And I only bring this up because, you know, as time rolls on, the landscape changes. I think the other measures that contextualize this one have changed. And that is why I just wanted to bring that to everyone's attention.

CO-CHAIR CROOKS: Okay. Other

comments on usability and use?

(No response.)

Unintended consequences? No?

Okay. Let's vote.

MS. OGUNGBEMI: We are now voting on Measure 2979, usability and use. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. Voting is open.

(Voting.)

Results are 26 percent high, 68 percent moderate, 5 percent low, and zero percent insufficient. Measure 2979 passes on usability and use.

CO-CHAIR CROOKS: So now, we are ready to vote on accepting the measure, endorsement of the measure.

MS. OGUNGBEMI: Yes.

CO-CHAIR CROOKS: Suitability for endorsement. Thank you.

MS. OGUNGBEMI: We are now voting on 2979's overall suitability for endorsement. Your options are 1, yes, and 2, no. Voting is open.

(Voting.)

Results are 79 percent yes, 21 percent no. Measure 2979 is recommended for endorsement.

CO-CHAIR CROOKS: Okay. Thank you, Committee. Thank you for great discussion.

We will now take a 10-minute break.

(Whereupon, the above-entitled matter went off the record at 2:08 p.m. and resumed at 2:20 p.m.)

CO-CHAIR ANDERSON: Okay. If we can all get back together, so we can restart?

We are going to be starting with 0369, which is the Standardized Mortality Ratio, and Lorien has a conflict. John, Ishir, Peter, and Josh are the reviewers.

MEMBER BHAN: So, I am going to lead this off. This is just a frame. This is an existing --

CO-CHAIR CROOKS: I'm sorry, we are shortcutting the process.

CO-CHAIR ANDERSON: Right.

CO-CHAIR CROOKS: Hold that thought.

(Laughter.)

MEMBER BHAN: Thank you. Thank you.

DR. WHEELER: Good afternoon. I'm Jack Wheeler. I'm an economist at the University of Michigan. This is my colleague Claudia Dahlerus, who is a research scientist at the U of M.

We have nephrology and statistics expertise in the back of the room, as you have already heard from, and we may be calling on them as we go.

The standardized mortality ratio for dialysis facilities was developed by the University of Michigan Kidney and Epidemiology and Cost Center over two decades ago, and it has been in use in the dialysis facility reports since 1995. They received initial NQF endorsement in 2008, and it has been improved substantially over the years, thanks, in part, to the review process established by NQF.

These improvements have enhanced the measure's feasibility and usability, and these

endorsement criteria are well-supported by its use in public reporting in Dialysis Facility Compare since 2001, and by notable reductions in mortality associated with dialysis patients over the years.

Since the last endorsement by NQF in 2012, we have made four changes to the standardized mortality ratio. Most specifically, the risk-adjustment model now includes adjustment for 210 prevalent comorbidities, as reported on Medicare claims over the previous calendar year, in addition to the incident comorbidities reported on the medical evidence form.

The inclusion of prevalent comorbidities as adjusters is partially in response to comments received from a broad range of stakeholders over the past few years. These stakeholders made the point that adjustment for prevalent comorbidities was necessary to reflect a more timely assessment of the patient's health status.

In response to these comments and

suggestions, and with the support of CMS, U of M KECK conducted several analyses of potential ways in which prevalent comorbidities could be included in the risk-adjustment model. These analyses informed the work of a Technical Expert Panel in 2015, and the TEP developed a set of recommendations for the inclusion of specific prevalent comorbidities as risk-adjusters in the SMR. Both the process followed by the TEP and all of its resulting recommendations were supported by TEP members with strong consensus and in several cases unanimity.

In the development of the revised SMR that is described in the NQF materials, U of M KECK implemented fully and without alteration the TEP recommendations. This changed review is essentially improving the face validity of the SMR.

A second change to the SMR is that it pertains to Medicare patients only. This change was supported by the TEP as necessary to enable the use of Medicare claims data to reflect

prevalent comorbidities.

Third, the risk-adjustment model now adjusts for each incident comorbidity separately rather than through the use of a comorbidity index, as in the past. This change was made for consistency in the handling of incident and prevalent comorbidities.

And fourth, the indicators for diabetes from the medical evidence form have been consolidated into more meaningful incident comorbidity adjusters.

We look forward to your review of the SMR today. Thank you.

CO-CHAIR CROOKS: Okay. Thank you.

MEMBER BHAN: So, apologies for my overexuberance in getting started.

(Laughter.)

As nicely summarized, we are dealing with a previously-endorsed measure. In terms of the evidence, there is a great deal of evidence.

Actually, to summarize the measure again, just so we are all on the same page, the

measure is a standardized mortality ratio, but it is mentioned that it can also be calculated as a rate. And the rationale is that dialysis patients die at high rates and that high mortality is a less-than-desirable outcome. And so, it is used as the measure here.

The numerator is the number of deaths among eligible patients at the facility during the time period. The denominator is the number of deaths that would be expected among eligible dialysis patients. As mentioned, there are numerous covariates that are used for adjustments here.

The measure type is an outcome, and data sources are administrative claims and electronic clinical data. And the level of analysis here is at the facility level.

So, it is mentioned that the SMR is typically expressed as a ratio, but it can also be calculated as a rate. And so, I think the way I like to frame this is, if you look at the algorithm -- and this is mentioned with the last

topic we covered -- the initial question is, does the measure assess a performance on health outcome? I think most people would agree that mortality is a health outcome. And then, is there a relationship between at least one healthcare action, structure, process, intervention, or service, that can influence that outcome? Now there is a great deal of evidence provided here, a lot of, admittedly, retrospective and observational, but some prospective analysis as well, looking at various different factors that are associated with mortality rate. And the way I thought of this was, conversely, if we say, is there nothing we can do to affect the mortality, I would think that most people would probably say that is not accurate.

So, given that this is an existing measure, I will stop there and let anyone jump in, if they feel like they need to.

MR. LYZENGA: And just to clarify, you do have the option of sort of skipping over and

foregoing a vote on evidence, since this was approved by the previous Committee. So, with the Committee's consent, you may do that if you feel that is appropriate.

CO-CHAIR CROOKS: Forego the vote is sort of like voting yes, I suppose.

CO-CHAIR ANDERSON: Alan has some comments. Alan?

CO-CHAIR CROOKS: Alan? Dr. Kliger?

MEMBER KLIGER: So, I think if you follow the algorithm, I think that there is no question that it is an outcome measure and there is no question that there are some factors that relate directly to that outcome.

So, strictly looking at this algorithm, if that is the way we are going -- and that is what we did with the last one -- I would have to agree with you that we say this is a pass here.

However, I again want to raise the concern that we are developing measures that we want to have of utility for clinicians to improve

overall care for patients. I still find that the evidence that the mortality rate itself is substantially affected by things that we clinicians actually can manipulate is relatively small, that the vast majority of this outcome, which is perhaps the most important outcome to patients, is determined by factors other than things that we control. And while we surely can have a wider set of comorbidities adjusted for, and that is very helpful in this context, that, nonetheless, if they are the controlling factor and there is only a very small amount of difference that anything that we do makes, then it is an insensitive tool to use for quality improvement.

And so, again, we are going to pass this and we are going to go through the discussion quickly, my guess is, but I just need to again register my concern that, as a measure of utility for quality improvement, that I find it to be a very blunt instrument.

CO-CHAIR ANDERSON: Andrew?

MEMBER NARVA: It is interesting, I think that physicians or providers may not be convinced that they can have a big impact, but I think most patients do. In the sense that this is a patient-centered outcome, not because it is their death, but just because it is a concern of patients, I think it just changes the perspective.

My experience, just when I oversaw lots of dialysis units for Indian Health Service, was, when there was a flurry of deaths, the patients were very concerned about whether that reflected a quality difference. And that was the one time you would really get a grassroots question. And so, it is not exactly the way we approach things, but I think patients would like to have this information, would like to know that someone is looking at it.

MEMBER HARTWELL: Hi. This is Lori Hartwell. I would just like to chime-in.

Just to the comment, just hearing that there is very little ability to change, isn't

there improved survival rate with home dialysis and nocturnal dialysis? And this is important to patients. So, I just wanted to throw that out there, and what was the response? You know, that improving mortality, and if more patients would choose those treatments, we might have better outcomes.

MEMBER BHAN: And I think one of the tricky things has always been, if you look at observational data, people will critique it and say, "Well, those are observational studies," "They're retrospective studies," "They're prone to residual confounding." But, yet, the prospective trials are selected populations. They are not generalizable. So, I think it is just a very difficult thing to know for sure what the answer is here.

I will note that the NKF did put a comment in saying they do not support this measure because it does not clearly encourage quality improvement or provide meaningful information to patients. And a lot of that was

based on comorbidities. Now there is a great deal of adjustment here. There will always be people who argue that it is insufficient. And then, there is a question of what exactly can be done and should we focus more on more specific measures, to Alan's point. But I don't know that there will ever be adequate resolution along those lines.

CO-CHAIR ANDERSON: Frank?

MEMBER MADDUX: So, I would just like to ask Jack and Claudia a question about, as we think about the life cycle and evolution of this particular measure and we realize that we are moving from dialysis care to broader care of the patient fully that has end-stage renal disease, we will move into an environment where there are many more patient-centered options and goals that patients choose. And so, how will this measure play, as we have progressively more patients that elect to dialyze not for rehabilitative reasons, but for other reasons that may not be commensurate just with length of life?

DR. WHEELER: Frank, I'll answer as an economist and, then, maybe turn to my nephrologist colleagues.

I think you're right, I mean sort of expanded definitions of the bundle and the CEC, and all we're going toward, will change the way patients think about their care and providers think about the care for sure.

I do think that we are always going to want some kind of mortality metric. It will perhaps evolve and be associated with different mixes of care. But I think we are always going to want to track mortality and see how it is going, allow us to evaluate facilities.

And I will see if anybody else wants to chime-in there.

MEMBER HARTWELL: I'm just curious because this is kind of a new conversation where this wouldn't be a potential measure. How do nursing homes handle it? And as a patient, whenever I look at like a transplant center, I look at the success rate overall. So, how would

one determine the success rate? And I understand there is an older population and there might be some palliative care involved. Just for my own knowledge, I would be curious to know.

CO-CHAIR CROOKS: So, Lori, what is it that you're asking? Can you be a little more specific?

MEMBER HARTWELL: Well, we are discussing this measure on mortality, and I am just surprised that it is not considered important. This is the first I have really heard that conversation. So, it is all new to me.

As a patient, this is something that is very important. This is how you can really determine a success rate. Now I understand that we are moving to more integrated care models. Palliative care is becoming a topic of discussion. So, again, you wouldn't want somebody to skew -- you know, keep somebody who doesn't choose to be on dialysis and, then, decide that they need to be to make these measures. So, I do understand that.

I'm just trying to absorb what was just said, and I'm speaking outloud right now. So, maybe I don't have a question, if anybody can add --

CO-CHAIR CROOKS: Right. Okay. Well, I would reassure you that I don't think anybody is saying the measurement of mortality is not important. I think it is important.

What is difficult is which audience is looking at it and what can be done by clinicians to improve it. That is always, you know, from a physician's point of view, is it the most useful to know that your dialysis unit's mortality is a little low? It doesn't tell you exactly what you need to do fix the problem or to improve it. But nobody is saying it is not important, and that in the future, even as healthcare systems evolve, we won't want to keep looking at that, or its converse, which is survival.

DR. MESSANA: So, Dr. Maddux, I think it is a great question. We have talked over the phone recently about these kinds of things. And

I think you hit on a critical point.

We also talked about the difficulty in developing those kinds of metrics and how far off they are. Even after those metrics that evaluate the sensitivity of a facility to patient decisions and what the patient's goals are, there are opportunities to game systems by how one defines or how one presents that information or those data to patients.

And so, I agree fully with Jack that, as long as we are in the business of spending the kind of effort we do each year to have people on dialysis, that survival on dialysis is one of the primary metrics. Certainly, how successfully we achieve patient goals is something that is also going to be very important down the road. How long it takes us to get there is the real question.

DR. WHEELER: I would just add one more thought. So, the unit of analysis for a mortality ratio or the unit of responsibility, let's say, may evolve in response to some of the

factors that you are talking about as well. That makes sense to me.

CO-CHAIR CROOKS: Rick?

MEMBER KASKEL: Excuse me. Maybe I'm missing something, but there are so many factors here and variables that I'm not seeing that kind of affect the outcomes that you are looking at.

For instance, the demographic characteristics of the unit and the facility, how is that standardized here? Innercity, rural, suburban? I mean, is that somehow standardized in this equation, in this analysis?

DR. WHEELER: So, we standardize for the demographics, some demographic characteristics of the individual patients, but not the sort of market or area-level of measures that I think you are referring to, at least at this point. We evaluated whether that was a good idea and at this point concluded that it wasn't.

MR. LYZENGA: We may want to hold off on that discussion until the validity section.

MEMBER WAGNER: Could you just

summarize for us what you believe the more robust case-mix adjustment and the elimination of non-Medicare patients does to this measure with respect to the outcomes?

DR. WHEELER: Would you mind waiting until we get to validity?

MEMBER WAGNER: Oh, okay.

DR. WHEELER: Because it is sort of more properly within that category.

MEMBER WAGNER: Because I am just worried that, if we rush through this, as people have argued that let's just say this is the same measure, then we will not have that discussion.

MEMBER ZARITSKY: I think there will be a lot of discussion on validity because I think my honest opinion is it overmodeled when you look at the details. So, we will get to all of that, but I think we should vote on the evidence. But I think that is going to be one of the easier things.

MR. LYZENGA: It sounds like the sense of the Committee is not to skip over the

scientific acceptability portions, and we will have some discussion there.

I guess we still have the question, do we want to vote on evidence or not? Maybe we should do that by exception. Is there anybody who does want to vote on evidence?

CO-CHAIR CROOKS: Right. If you would like to have a vote on evidence, please raise your hand.

(Show of hands.)

Okay. I'm getting a lot of this. Okay. Let's vote on the evidence. I think that is what the Committee would like to do.

MS. OGUNGBEMI: Okay. We are now voting on Measure 0369, Standardized Mortality Ratio for Dialysis Facilities. We are voting on evidence for health outcome measures. Your options are 1, yes; 2, no. Voting is open.

(Voting.)

Results are 89 percent yes and 11 percent no. Measure 0369 passes on evidence.

MEMBER BHAN: Okay. So, let's go on

to the performance gap here. Here the developer presented SMR data for dialysis facilities, and there was quite a degree of variation where the mean, of course, is 1.02, but the 10th percentile went down to .05 and the 90th percentile went to 1.5. That is over the 2010-to-2014 time period.

And in terms of disparities, this is a little bit tricky. The developer mentioned, if you look at various different demographic, for example, Hispanic patients have lower mortality than non-Hispanic; whereas, female patients have lower mortality as well than male patients. Although these are included in the adjustment, so that is not really a disparity in the SMR per se, but, clearly, my feeling was that there will always be a performance gap in terms of mortality. But I appreciate there is a variety of opinions on this. But I will let anyone else comment.

CO-CHAIR CROOKS: Okay. Any other discussion?

(No response.)

I would say that the disparities just demonstrates gaps, and that is what we are voting on right now. So, that is a different topic than whether or not or how you adjust.

So, let's vote on the presence of the performance gap.

MS. OGUNGBEMI: We are now voting on performance gap for Measure 0369. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. Voting is open.

(Voting.)

Results are 26 percent high, 68 percent moderate, zero percent low, and 5 percent insufficient. Measure 0369 passes on performance gap.

MEMBER BHAN: Okay. So, let's move on to reliability. Just as a reminder, the numerator here is the number of deaths among eligible patients at the facility during the time period, and the denominator is the number of deaths that would be expected among eligible dialysis patients at the facility during the time

period, given the various adjustments that are detailed extensively.

So, the key thing here, since it is an existing measure, are the changes to the measure since the last time. As mentioned by the developer, there are four key changes. One is the model now adjusts separately for each comorbidity rather than using an index. Two is the indicators for diabetes were consolidated from the individual indicators.

I think that two more important or more dramatic changes are, No. 1, the adjustment for 210 prevalence comorbidities, instead of just the incident comorbitidies from 2728, are now included; and that the measure is now limited to Medicare patients, which should make the data collection a little more reliable, and the data from the first 90 days is not included, therefore.

So, I will pause there for any questions or comments.

(No response.)

So, moving on to some comments on the reliability testing, the developer looked at the degree to which the SMR data was consistent from year to year. If you look at the data, it is fairly consistent from year to year. There is also some data provided -- now this came up with a previous discussion -- on not only the effects over time, but the reliability testing based on the size of the facility.

And here there is -- I don't know if we can pull that up on this screen -- if you look at the IURs for the three-year measures, they are overall on the low side, suggesting that there is a good deal of differences that can be attributed to noise. And that is particularly evident for these smaller dialysis units.

So, just to give you some numbers here for 2010 -- that is 2013; yes, there we go -- you can see these numbers, we were critiquing numbers that were .5 in the last measure, but these are consistently below .5, until the four-year SMR data was looked at collectively.

So, in the previous data you can see, especially in the small units, the numbers are .07, .06, .03, and even across four years, .3. So, that was a little bit of a concern for me, but that is the nature of the data.

MEMBER FISCHER: I actually had a question about this, and maybe to the developer. With the STR, the year-to-year data is similar for an aggregate of three- or four-year data. For here, it is much different. You could just pick 2013, right, where it is .10 to .4, but the aggregate four-year is .3 to .73. I didn't review this in-depth, but I was trying to understand how the aggregate four-year values are so different from year-to-year values, particularly in contrast to the measure that I reviewed in detail. And perhaps there is a simple explanation, but I was just curious if the developers had a comment.

DR. WHEELER: I'll start.

MEMBER FISCHER: So, yes. No, no, you have year-to-year data. Yes, there is no

aggregate like over four years.

But I guess what is interesting is why -- anyway, I guess one question that just remains for me is why there is such a difference in an annual value versus a four-year composite value.

DR. WHEELER: It's principally just a matter of sample size and the very low frequency of mortality in the population relative to, let's say, transfusions, which are much more frequent.

Doug, do you have anything more to say about that?

DR. SCHAUBEL: No, that's it.

CO-CHAIR ANDERSON: Go ahead, Frank.

DR. MESSANA: So, mean transfusion rates are about .45, .47, right? I mean, it is not evenly distributed. But transfusion events on average are much more common than death, which is 15-18 percent, something like that, and I am told that it affects these calculations. They are very sensitive to the numbers.

CO-CHAIR ANDERSON: Frank?

MEMBER FISCHER: But this measure is

an annual reported measure, correct?

CO-CHAIR ANDERSON: Yes.

MEMBER FISCHER: So, in other words, the ones that are the most relevant, when you think about reliability, would be the year-to-year values.

DR. DAHLERUS: So, what is reported on Dialysis Facility Compare's four-year measure?

CO-CHAIR ANDERSON: Frank?

MEMBER MADDUX: I think, Michael, from just observing a lot of clinics over time, there are more than a few clinics that will have exceedingly good scores for a few years and build up, essentially, a supply of older and older, longer vintage dialysis patients that ultimately die, and they will, almost predictively, go down if they have two or three exceptional years. Now that may not be what you all see statistically, but this is not inconsistent with what my observations have been in a large population of facilities.

CO-CHAIR CROOKS: Well, I, for one, am

very troubled by the low reliability of this measure, especially the one-year measurement where, even in a large facility, your variation -- I may not be interpreting this right -- but it is 50/50 chance that it is actually due to something you are doing in your unit versus noise. And it is nice to hear that it is reported as four-year where the reliability does go up, but the measure, as written, is a one-year, not a four-year.

DR. DAHLERUS: Either. It could be calculated either --

CO-CHAIR CROOKS: Either? It could be either way?

CO-CHAIR ANDERSON: Michael?

MEMBER SOMERS: Even with four-year, I mean, if you look at the number of facilities, and 60 percent of the facilities are going to fall either in the small or the medium categories, and they have IURs that are quite low. So, it is hard to be enthusiastic about something that may not be reliable for 60 percent

of facilities.

CO-CHAIR CROOKS: So, other comments on reliability?

(No response.)

Does this Committee feel ready to vote on reliability? I guess they are.

MS. OGUNGBEMI: We are now voting on reliability for Measure 0369. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. Voting is open.

(Voting.)

Results are 5 percent high, 16 percent moderate, 74 percent low, and 5 percent insufficient. Measure 0369 fails on reliability.

MR. LYZENGA: So, that is, again, a must-pass criterion. The measure will not move forward. We can, again, provide some feedback to the developers if we have any thoughts on how they might improve the measure, if they would like to bring it back to us for consideration.

MEMBER ZARITSKY: Just one thing I noticed, and a lot of the outside groups

commented, that you might have gone a little too far with your modeling; that you look at some of the -- you know, there's some strange stuff that pops up when you include so many different variables, like thyroid cancer is protective. It appears to be overmodeled.

And I think that most of us agree that this is, you know, a valid, I consider it a valid measure. Especially patients want to know what the -- maybe not the rate; they want to know the rate versus the ratio. But it seems like, for the larger units, you do have a good four-year -- you know, .7 is adequate. So, maybe it needs to be restructured for larger groups.

MEMBER BHAN: Yeah, I just want to emphasize that it seems like the main hangup here was this IUR. So, restricting to four-year data may be a way to deal with that.

MEMBER KLIGER: Can I just underline the comments about thinking about this as a rate rather than a ratio? Because, obviously, mortality is important; it is important to all of

us. But, if we are focused on the way patients are seeing it and what patients are responding to, then the rate is going to be far more valuable to them than is a ratio.

DR. WHEELER: Thank you.

A couple of responses. First of all, the numbers of comorbidities, the 210 additional prevalent comorbidities, you find that as generally an improvement. But I think it is important to look at the comorbidities taken as a whole and their effect, rather than some of the individual coefficients.

The TEP did --- the goal of the TEP was to include all relevant comorbidities that might not be under the control of the facility, and that was kind of the tenor of their discussion. And so, we did that in terms of our modeling, just as one response.

A second question I would ask is, if we had offered this as a measure that was only a four-year measure, would the numbers that you see here in terms of reliability have carried the day

or would there still be kind of a level of reliability that is insufficient?

And I'll get to your question in a second.

CO-CHAIR ANDERSON: John? John?

MEMBER WAGNER: So, I just will respond to that and will ask my question. I would be concerned, since we don't have the data, what the medium- and small-sized IUR, if combined together, what their IUR would be over a four-year period as well. Because, again, we are talking about 60 percent of the facilities may have a very high noise ratio compared to signal.

I want to, again, pose the question I asked at the outset because I suspected we would get to this point. What is, in fact, with this what some have termed "overmodeling of the data," has that actually reduced the IUR compared to the previous? And the elimination of the Medicare, rather elimination of the non-Medicare population, has that impacted these data in a meaningful way?

DR. WHEELER: We did look at the effect of including or adding the 210 prevalent comorbidities on the IURs, and, yes, there was an effect; that does lower the IURs from what it would be if we didn't adjust for all the prevalent comorbidities.

In terms of the tradeoff with Medicare, I don't think we did look at the effect of excluding Medicare on the reliability measure analyses that we did. Okay?

Sorry, was that responsive to your question? Okay.

In terms of the rate versus ratio, we could convert the ratio into rate by applying the national average, and that is the way Hospital Compare does it. It seems meaningful. And there are reasons for us to use a ratio approach that, again, have to do with the rare event, relatively rare event of mortality and also hospitalization, which we will talk about in a minute. So, that is the reason we do the ratio, yes.

MEMBER KLIGER: I understand the

rationale.

DR. WHEELER: Okay good.

MEMBER KLIGER: And to a scientist, that would be clear, or to a clinician, I believe. But, to our patients, I think it would be perhaps more useful to have a rate.

DR. WHEELER: Right.

CO-CHAIR ANDERSON: Michael?

CO-CHAIR CROOKS: Michael, you had your card up?

CO-CHAIR ANDERSON: Oh. That's fine.

DR. DAHLERUS: I did want to clarify that it will be reported as a rate in the future on Dialysis Facility Compare for the purpose of providing something interpretable to patients.

CO-CHAIR CROOKS: Okay?

MEMBER LATTS: Can I just ask a quick question?

CO-CHAIR CROOKS: Yes.

MEMBER LATTS: I'm just wondering what the sort of practical implications are of this not being an approved NQF measure. I mean,

obviously, CMS is going to keep using it, right?

CO-CHAIR CROOKS: Well, our turnaround time used to be four years before the Committee would meet again. Now we are a standing committee. So, I suppose the implication is, if this can be improved and the reliability improved, you know, we may not have to wait that long.

But what do you see as the -- you are asking what are the negative consequences of it?

MS. SAMPSEL: But, you know, I also, just as a reminder, this is this step in the process. We still have public comment. This would go out for public comment. It still included in the draft report for public comment. And then, you could also ask for a reconsideration request.

So, you know, we have heard you say that this is already a four -- you know, it is implementable or operationalizable as a four-year reportable measure. And so, if you can adjust anything that you have heard from the Committee

and, thus, want to ask for a reconsideration, you can do that during public comment.

CO-CHAIR ANDERSON: All right. Moving on to the Standardized Hospitalization Ratio, it is Stuart, Franklin, Karilynne, and Andrew.

And we will hear from our measure developer first.

DR. WHEELER: Thank you.

This will be a brief introduction. The Standardized Hospitalization Ratio was also developed by the University of Michigan KECK over two decades ago. It has been included in the Dialysis Facility reports since 1995. It received initial NQF endorsement in 2011, and it also has been improved substantially over the years.

The changes that we have put in since the 2011 endorsement are the same ones that we had for the SMR with one exception. The SHR was always about Medicare patients only. So, that change has not been made. But we did, as with the SMR, we did add 210 prevalent comorbidities

in response to stakeholder requests and the work of the TEP. So, those are our main changes.

CO-CHAIR ANDERSON: All right. Who is taking the lead on this one?

MEMBER GREENSTEIN: I guess I am. Not sure why they're certain, but that's all right.

Anyway, so this is a measure, as was mentioned, that has been reported previously. As was mentioned, the hospitalization rates vary among the chronic dialysis units. Even though there has been a decline in the general population, in the dialysis patients we have not seen the same kind of decline.

In addition, the USRDS Annual Report for 2015 showed that approximately half of all the dialysis patients continue to have hospitalizations due to factors such as cardiovascular infections and diseases.

Programs that were developed to impact upon hospitalization rates included catheter usage and other things that have clearly impacted upon the hospitalization rates. And here, I

guess the real question was that this is clearly health outcome process that we are looking at, not using the word "process" though, but health outcome. And the question was here whether or not we should just go straight to an endorsement since it was previously endorsed versus should we go through a complete review, just like we did on the SMR. I am curious to see what everybody is going to say, given that the SMR was knocked out.

So, with that, I'll start from there.

CO-CHAIR ANDERSON: So, shall we vote on whether to pass or not? On evidence? I'm sorry. On evidence?

Any comment? Any further comments? Yeah, Alan?

MEMBER KLIGER: If you follow the algorithm, it has to be passed.

CO-CHAIR ANDERSON: Yeah. Good comment.

MR. LYZENGA: Is there anybody who would like to vote?

So, call for a vote.

MS. OGUNGBEMI: We are now voting on Measure 1463, Standardized Hospitalization Ratio for Dialysis Facilities, and we are voting on evidence for health outcome measures. Your options are 1, yes; 2, no. Voting is open.

(Voting.)

We are waiting on one more vote. Could everyone just point and click one more time? Thank you.

(Voting.)

Got it.

Results are 95 percent yes and 5 percent no. Measure 1463 passes on evidence.

CO-CHAIR ANDERSON: Okay. Moving on.

Oh, turn your microphone on.

MEMBER GREENSTEIN: So, we're moving on to -- what's that? Gap, right, let me just bring up my computer, so I can read it easily.

The developer mentions that there is variations across facilities and that race and ethnicity have shown to be predictors of hospitalization rates, and they felt that there

was a gap, which appeared to follow through from the comments from all the people.

CO-CHAIR ANDERSON: Any questions for the developer or further comments? Yes, Frank?

MEMBER MADDUX: So, I have a question for Jack and Claudia. We know there are a lot of probably covariates that may relate to hospitalization rates. I'm just wondering how extended you have gone in your adjustment for those geographies and other such things.

DR. WHEELER: Well, again, we didn't adjust for geography. We did adjust for patient characteristics. As noted, we adjusted for a large number of patient comorbidities and age and sex. Basically, yeah, we did not adjust for true geography, but we did evaluate whether geographic characteristics were something we wanted to adjust for. Measures such as the per-capita income in a zip code and educational levels in a zip code or unemployment, and those sorts of characteristics, we did look at those.

CO-CHAIR CROOKS: You did look at

those?

DR. WHEELER: Yes.

CO-CHAIR CROOKS: Okay.

DR. DAHLERUS: Just to elaborate on Jack's answer, so we evaluated area-level socioeconomic status as well as patient-level SCS, in addition to demographic factors. And those results are reported in the testing section. But the bottom line is area-level factors had very little impact on SHR, and especially when you look at flagging with and without those adjustments.

CO-CHAIR ANDERSON: Any further discussion?

(No response.)

Are we ready for the vote? All right.

MS. OGUNGBEMI: We are now voting on performance gap for Measure 1463. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. Voting is open.

(Voting.)

Results are 37 percent high, 63

percent moderate, zero percent low, and zero percent insufficient. Measure 1463 passes on performance gap.

CO-CHAIR ANDERSON: All right. Reliability.

MEMBER GREENSTEIN: Just give me one second. My computer did a funny thing. Yes, let me get to where it is.

In terms of reliability, the developer assessed the degree to which the standard hospitalization rate was consistent from year to year using data on hospitalizations among the patients, and the developer stated the measure is based on complete data and is not subject to judgment or rate of variability. Any variability was related to some noise evidently. And they did throw in now comorbidities to go into the analysis. So, most of the comments were that it was felt that reliability was good and there were no concerns, with the overall IUR being in the .70 range.

CO-CHAIR ANDERSON: Any comments or

questions?

(No response.)

Are we ready to call for the vote?

MS. OGUNGBEMI: We are now voting on reliability for Measure 1463. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. Voting is open.

(Voting.)

Results are 26 percent high, 68 percent moderate, 5 percent low, and zero percent insufficient. Measure 1463 passes on reliability.

CO-CHAIR ANDERSON: And validity, moving on?

MEMBER GREENSTEIN: So, the validity was assessed using data on hospitalizations as well as other quality measures over a three-year period by examining its covariability as well as by examining the relationship of overall hospitalization measures with measures that were more directly focused on specific causes.

And the validity was tested with results indicating correlation to IUR. We

officially standardized modality rate. And for the most part, the comments were that validity was supposed to correlate in terms of this also.

CO-CHAIR ANDERSON: Any questions for the developers or further comments?

(No response.)

All right. Let's call for the vote for validity.

MS. OGUNGBEMI: We are now voting on validity for Measure 1463. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. Voting is open.

(Voting.)

Results are 32 percent high, 68 percent moderate, zero percent low, and zero percent insufficient. Measure 1463 passes on validity.

CO-CHAIR ANDERSON: All right. Moving on to feasibility?

MEMBER GREENSTEIN: So, feasibility. I think, for this, again, there were no comments. They felt that the data elements were fairly well

defined in electronic form and generated and collected so that there was no problem with feasibility. And we have no comments, either, on this.

CO-CHAIR ANDERSON: Any further questions or comments for discussion?

(No response.)

All right. Call for the vote.

MS. OGUNGBEMI: We are now voting on feasibility of Measure 1463. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. Voting is open.

(Voting.)

Results are 74 percent high, 26 percent moderate, zero percent low, and zero percent insufficient. Measure 1463 passes on feasibility.

CO-CHAIR ANDERSON: And use and usability.

MEMBER GREENSTEIN: So, usability, the measure is publicly reported nationally, Dialysis Facility Compare, and the standard

hospitalization ratio measures/incorporates risk-adjustment technology that levels the field for different size units. And therefore, it was felt to be a reasonably usable result.

CO-CHAIR ANDERSON: Any further discussion or comments?

(No response.)

All right. Call for the vote.

MEMBER MADDUX: I have a question.

CO-CHAIR ANDERSON: Oh, I'm sorry.

MEMBER MADDUX: So, can you all just comment and expand a little bit on the discussion that you had around the relationship between SHR and SRR? Interrelationship seems fundamental if they are both going to be used because they are going to run together.

DR. DAHLERUS: So, we considered them certainly related, but also complementary in terms of assessing facility management of patients in terms of preventing hospitalizations or preventing a readmission after a patient is discharged from the hospital.

So, while there is overlap, we don't think that they are measuring exactly 100 percent of the same thing. So, we are making an assumption that there are things that the facilities can do to prevent an unnecessary hospitalization, and that there are things related to care coordination that should happen after a patient is discharged from hospital in order to prevent a readmission.

MEMBER MADDUX: And have you studied statistically the impact on the SRR from an improved index hospitalization rate?

DR. DAHLERUS: I'm not sure I quite follow what you are asking.

MEMBER MADDUX: Clinically, when we focused on a lot of care coordination activities around avoiding readmissions, one of the correlates that we saw was reduced index hospitalizations --

DR. DAHLERUS: Uh-hum.

MEMBER MADDUX: -- which seems odd, but, in fact, happened. And so, I'm just curious

if there's been any way that you have had more broadly to analyze just the interrelationship of affecting one that may have impact on the other.

DR. DAHLERUS: And how that impacts the other?

MEMBER MADDUX: Yes.

DR. DAHLERUS: We haven't studied that extensively.

CO-CHAIR ANDERSON: Any further discussion?

(No response.)

All right. We're calling for the vote.

MS. OGUNGBEMI: We are now voting on usability and use for Measure 1463. Your options are 1, high; 2, moderate; 3, low, and 4, insufficient. Voting is open.

(Voting.)

Results are 42 percent high, 58 percent moderate, zero percent low, and zero percent insufficient. Measure 1463 passes on usability and use.

CO-CHAIR ANDERSON: All right. Oh, now for the overall vote for suitability for endorsement.

MS. OGUNGBEMI: We are now voting for Measure 1463's overall suitability for endorsement. Your options are 1, yes, and 2, no. Voting is open.

(Voting.)

Results are 100 percent yes and zero percent no. Measure 1463 passes on its overall suitability for endorsement.

CO-CHAIR ANDERSON: All right. Andrew, the discussion for the NQF Measure --

DR. WHEELER: I just want to thank the Committee very much for your comments and suggestions. Thank you.

CO-CHAIR ANDERSON: -- Medication Reconciliation for Patients Receiving Care at a Dialysis Facility.

MR. LYZENGA: Yes. So, as I mentioned in my email to the group, this measure will be considered by the Patient Safety Standing

Committee at NQF, who typically has, sort of oversees our portfolio of, well, a range of patient safety measures, but including medication reconciliation measures. We have some other medication reconciliation measures in their portfolio and thought it best to keep this associated with those for things like harmonization purposes and just so we had some consistency.

But we acknowledge that there was not specific renal expertise on that Committee, although a pretty broad range of expertise in other areas and in patient safety generally. So, agreed with the developer of this measure that it may be useful to get some input from this Committee on the measure, and particularly if there are considerations that would be specific to the dialysis patient community.

It is a fairly straightforward reconciliation measure, but it would be helpful to know if there is anything that the Safety Committee should keep in mind during their

review, if there is anything that you would tell them from your perspective as renal experts.

And I believe we have the developer on the line here as well, if she wants to just give a quick introduction and explanation of the measure, and see if she has any questions, specific questions, that she would like answered. That is Lisa McGonigal.

Lisa, are you on?

DR. McGONIGAL: Yes. Yes, I'm on. Can you hear me okay?

MR. LYZENGA: We can.

DR. McGONIGAL: Okay, great. All right.

So, I am also joined today by Dr. Robyn Nishimi. Again, I'm Lisa McGonigal from the Kidney Care Quality Alliance, or KCQA.

Again, just thank you for taking the time today to lend your expertise and to provide your input on this measure as it is being considered by the Patient Safety Standing Committee in their project.

So first of all, just an overview. This is, again, medication reconciliation for patients receiving care at dialysis facilities. It is developed by the Kidney Care Quality Alliance. It is specified at the level of the dialysis facility, which makes it unique among measures contained in NQF's current medication reconciliation measure portfolio.

The measure is applicable to all patients permanently assigned to a dialysis facility. And it assesses the percentage of patient months for which medication reconciliation was performed and documented by an eligible professional. And for the purposes of this particular measure, the eligible professional is assigned as a physician, an RN, an advanced practice RN, physician's assistant, pharmacist, or pharmacy technician.

Then, in regards to the importance of the measure, as you all well know, medication management is a critical safety issue for all patients, but especially so for patients with

ESRD. These individuals often require 10 or more medications. They take an average of 17 to 25 doses per day. They usually have numerous comorbid conditions, have multiple healthcare providers and prescribers, and they undergo frequent medication regime changes.

Also, medication-related problems contribute significantly to the approximately $40 billion in public and private funds that are spent annually on ESRD care in the U.S.

So, in developing the measure, we first examined existing medication reconciliation metrics and considered how to create a measure that is similarly-feasible and that doesn't unduly burden the provider that also goes beyond a single-component checkbox measure.

So, rather than seeking a single yes-or-no checkbox that medication reconciliation was performed for a given patient in a given month, we have developed a unique measure as compared to other NQF-endorsed med rec measures that requires multiple elements to be met to be counted as a

success for the facility.

But, in addition to attestation that all known medications are reconciled by an eligible professional and the date that the reconciliation took place, we also require that the identity of the eligible professional be indicated, and we specifically design what must be addressed during the reconciliation process.

Testing and feasibility. The measure was tested using data from three KCQA member dialysis organizations. Each had the capacity to provide retrospective analyses from a data warehouse or repository.

Testing involved approximately 5,300 facilities, and there were slight differences, depending on the month of the study, and approximately 328,000 patients in each of the six months of the study, which was conducted from April through September of 2015. So, we had a lot of facilities and a lot of patients in the study.

Empiric testing using the data binomial method, which is at the measure score

level, was conducted and demonstrated that the measure is reliable and that the measure components can be collected. And validity testing was done, and the measure was judged as being able to distinguish good from poor quality.

So, with that just brief overview, I will turn the floor over to you guys for your discussion, and feel free to ask any questions.

CO-CHAIR ANDERSON: Andrew?

MEMBER HARTWELL: This is Lori Hartwell. I have a question.

Part of the reconciliation process, is time of day considered in the reconciliation process? It could just be helpful. Like you shouldn't take blood pressure medicine before dialysis and the time of day you're supposed to take your phosphate binder, you know, you're supposed to take it 15-20 minutes after you eat. Is that part of the reconciliation process?

DR. NISHIMI: Lori, this is Robyn.

No, that would be under a different measure, part of the review process. So, that

kind of detail isn't encompassed by the reconciliation measure.

CO-CHAIR ANDERSON: Andrew?

MEMBER NARVA: I think dialysis patients are probably the perfect storm of lack of interoperability of electronic healthcare platforms. And, I think it would be very possible to check off the box in good conscience and actually not have very good reconciliation.

I wasn't able to read the whole measure because I couldn't open it until just now. But how did you validate the reconciliation to the actual medications that the patients were taking? Did you actually have some way of validating that with looking at the actual bottles of medication or how was that done? Or was it done?

DR. NISHIMI: No, we used a face validity approach at the measure level. We did not validate the data at that level. I understand your concern.

MEMBER NARVA: My concern is that I

think this is critical, but it is possible you could have this measure and it not make a big impact because the actual reconciliation is not very high because the bar is not very high. And I don't know if there would be some way to build into it something that would move more towards validating that you actually have a true reconciliation. Because any of us ---

DR. NISHIMI: Sure.

MEMBER NARVA: You know, most patients see many different providers and it is clearly a real problem, even when you try to reconcile medications.

DR. NISHIMI: Sure. I understand the concern, and that was a concern of us as developers, but we did feel that this was the place to start, even at this level. We described in terms of the actual performance, the range of performance was zero percent in a facility in any given month to 100 percent. And obviously, over time one would hope to assess the quality of the reconciliation, which is what I believe you are

speaking to. But this is viewed as a starting point for medication reconciliation in this population.

I can't hear what is going on now. I don't know.

MEMBER LENNING: Okay. Can you hear me now? Aha.

I would just like to raise the thought around where is the indication that there is a conversation with the patient. I know we have many medication reconciliation measures that do involve that conversation and true med reconciliation is not solely comparing lists and lists from other providers. But you can only have true reconciliation when you have a conversation with that patient about the medications. You don't know what they truly are taking if it is just a prescription. They can have the prescription and not be using the medication.

So, I would just caution that perhaps there needs to be more consideration about that

conversation. Thank you.

DR. NISHIMI: Yes, we appreciate that comment. We actually developed a trio of measures, a pure medication documentation measure, which is, for lack of a better term, the sort of middle step in our measure set, which was medication reconciliation. And then, the medication review measure would really address that. And the group's feeling was at this point we should advance the middle step, which was the medication reconciliation measure.

But we don't disagree and we actually developed a review measure, which, obviously, has much more patient interaction, but that was not the measure that was advanced as the first step for this population.

CO-CHAIR CROOKS: Who's next? Alan? Michael?

MEMBER FISCHER: My question for the developer is, in order to meet this measure, my understanding is you would have to do med rec every month, regardless of whether a patient has

been hospitalized or not. And I was just curious, just thinking about, as we have talked about the other instruments that patients are completing, you know, how long on average did it take, or do you have an idea, did it take to do this for each patient, given the number of medications they are taking each month? And kind of what was the feedback from the patients or their caregivers, as the case may be, about doing this every month?

I mention this because we have a freestanding unit where we have a PharmD who does do this, and you get mixed feedback. And I would just be curious what the developer's experience was in their course of their preliminary data analysis.

DR. NISHIMI: We didn't specifically assess an issue of time burden, if you will, but there wasn't any real pushback. The fact that when we tested this in, you know, the several thousand facilities and that, it was a zero to 100 percent. And it told us that, in fact, there

are some or several that are doing this monthly. So, that did not seem to be a consideration when we tested it.

MEMBER KLIGER: So, just again a clarification. It still sounds to me like it basically is an attestation. It is an attestation with a datestamp on it perhaps, but it is attestation.

So, the difficulty, obviously, is that all of us -- I mean, I'm guilty. I sit in the Epic system and I frequently do attestation to that med rec. And , you know, I sort of have a look at the list and I say, "Yes." I mean, I'm guilty; I do it.

So, I wonder in the development of this measure if you have had the opportunity to actually observe or see what med rec really looks like outside of the attestation.

DR. NISHIMI: Again, we did not look at sort of the data element level, if you will, quality beyond the attestation. We relied on the attestation of qualified professionals that this

was done.

MEMBER KLIGER: Yes. Just a quick followup, which is that I personally agree with you that this is a really important first step and it is part of a series of measures which include engagement of the patient. I think that that is important.

But I think we all need to recognize that an attestation alone, as we mature in our approach to this, is not going to be sufficient. And we should be thinking about, and perhaps the developer should be thinking about, ways to improve the measure other than it being a pure attestation.

DR. NISHIMI: Yeah, and I can report that that's exactly the kind of conversation that the KCQA had and that this was, indeed, a first step, and an evolution will be necessary as we go forward.

CO-CHAIR CROOKS: This is Peter Crooks.

A couple of comments. Yes, that is a baby step, and there are other medical records to

reconcile, too. There is what the patient is taking. There is what the dialysis unit list says. There is a pharmacy list in one or more pharmacies. If they have an electronic medical record such as we have at Kaiser, that may be different.

Within Kaiser, the pharmacy and the one that the doctors use is all the same. And then, whether they go to a cardiologist or they go to whatever provider, we are all looking at the same medicine list, which is much better than it is in the non-Kaiser world where every physician is going to have their own medication list. So, it becomes infinitely complex to try to resolve all of those short of one common medical record.

We do have to, in order to close an account, we have to check off -- and this is in Epic, the same thing, right? -- and our lawyers told that, as long as you've looked at the medicines that are relevant to what you're taking care of, so the blood pressure pill that day or

something, then we can check the box off and we're covered.

So, the comment I really wanted to make is ways to validate. This is maybe step two or step three. But you can't go to the patient's house, I don't suppose, and watch them for 48 hours and mark down everything they do, as the optimal validation method.

But, short of that, a patient diary taken for several days might be a nice way to try to validate that what you're actually getting at the dialysis unit is close to what they are taking at home, a more expensive proposition. And what would motivate patients to do that, I don't know. But I am trying to help think of a validity test that I would find worthwhile and convincing.

End of comment.

DR. NISHIMI: Thanks. Appreciate it.

MEMBER KASKEL: Will this involve under 18? Will this population be under 18?

DR. NISHIMI: This is an all-patient

measure.

MEMBER KASKEL: So, how are you going to assess the infant or a caretaker for an infant or a child?

DR. NISHIMI: Well, if we were doing the type of validation that Peter just indicated, we would have to create a protocol that involved proxy reporting, I presume. But, as part of this particular measure, we had a representative from ASPN and it was judged that it was also important for the pediatric population. So, it is an all-patient measure.

MEMBER KASKEL: Okay.

CO-CHAIR ANDERSON: Frank?

MEMBER MADDUX: So, I would just make a comment and reemphasize that I think it is vitally important that we recognize there's a series of steps here, because figuring out where the real source of truth is on medications is not easy.

I think there are steps with the evolution of Surescripts and other things to

understand what has been filled. I think there are other steps that have got to include what was mentioned previously about talking to the patient, reviewing what is happening there.

And it just strikes me that, even though this may be a baby step, it is going to be important that somehow we get started with this because it is a big tree to put your arms around. And somewhere we are going to need to sort of get off the ground to start with.

So, it strikes me that one of the opportunities for a measure like this, even as an attestation, is to potentially embed a greater demand to look at one of these resources, whether it is a Surescripts or it is some other resource that looks across organizations and prescribing providers at what all has been filled, regardless of whether it is just in the nephrology world or the cardiology world or the pulmonary world, or where it is. And that is an opportunity with this part of the measure, I think, to actually create that kind of demand, getting to some of

the other things, hopefully, sooner after that.

CO-CHAIR ANDERSON: Michael?

MEMBER SOMERS: I just wanted to comment that, for each medication, you are asking for nine pieces of information, and three of those have to do with information about the medicine that has already been discontinued. So, I guess in the best of all possible worlds you would want to know all that information about the discontinued medication. But, since the main purpose of the reconciliation is to get an idea of what they are taking now, I'm not sure those data elements may be as worthwhile, especially since you tell us that "unknown" is an acceptable response.

DR. NISHIMI: Thanks. We will take that back to the group going forward as a potential modification.

CO-CHAIR ANDERSON: I just have a clarification question. You're talking about medication reconciliation and, then, you talk about medication management. And I want to make

sure we are on medication reconciliation versus including medication management because they are two very different things.

Pardon?

DR. NISHIMI: Yes, we consider the domain to be medication management, which KCQA had three candidate measures, one on documentation, one on reconciliation, this measure, and one on review. And the whole process was viewed as medication management, but the measure is for reconciliation.

CO-CHAIR ANDERSON: Okay. Thank you.

Any further questions for the developer?

(No response.)

Can I ask one more thing? Back when you have the criteria that you have listed for medication reconciliation, it was my understanding when I was reading it, if all the elements were not available, even though you could say "unknown," it would fail. And so, I'm concerned about -- can you explain that a little

bit more in terms of what does that mean?

DR. NISHIMI: For that patient for that month.

CO-CHAIR ANDERSON: So, if you didn't have all of the elements, that would fail?

DR. NISHIMI: The attestation.

CO-CHAIR ANDERSON: The attestation?

DR. NISHIMI: For that particular patient in that particular month, yes. It may be present for everyone else. Let's say there are 100 patients, and for one of your patients you failed to document allergy. Then, that particular patient would fail, but your other 99 patients would pass. So, for that patient-month, your score would be 99, not 100.

DR. McGONIGAL: And also, knowing that if you try but you cannot find the information, "unknown" is an acceptable response. You won't fail if you put "unknown".

CO-CHAIR ANDERSON: And have you made any accommodations for communication with non-English-speaking patients or those that have

dementia? Or, certainly, it is easy to do medication reconciliation with SNFs or wherever the patient might reside, but what about those other patients? Have you thought about that?

DR. NISHIMI: This measure is not just risk-adjusted. I would think that for medication review, the measure that focuses to a greater degree on patient interaction, that will potentially be a concern, sure.

CO-CHAIR ANDERSON: Any other comments or questions?

(No response.)

Okay.

MR. LYZENGA: All right. Thanks to everybody. That will be very useful feedback for the Safety Committee.

Shall we move to the gaps discussion?

CO-CHAIR CROOKS: Yes. Okay.

Thank you very much and good luck with that.

MR. LYZENGA: Yes, thanks, Lisa.

DR. McGONIGAL: Thank you, everyone.

MR. LYZENGA: All right. So, with respect to gaps, as I mentioned, we have a list of the measures in the portfolio that I believe we passed out to you. I don't know if anybody has had a chance to look. But we would like to take just a few moments to see if the Committee has any particular thoughts on gap areas within this topic area, you know, measures that you think are lacking in this area or where you think we are lacking measures in this particular area.

That could be on a particular topic area. That could be types of measures. Maybe you think we need more outcomes or more patient-reported outcomes. Maybe you think we need different levels of analysis, sort of any type of gap that you think we are facing in terms of measurement on the topic of renal care.

This is important for us because we do try to feed this kind of information back to our developer community. We are also trying to take more of an active role as NQF in identifying gaps and prioritizing gaps across the measurement

enterprise. So, it is very useful information for us as well. So, we would welcome any feedback you have on sort of the state of renal measurement and where there are some important gaps.

MEMBER HARTWELL: Hi. This is Lori Hartwell.

One of the measures that I have been proposing for many years, although I think it would be a little labor-intensive and I don't know where you would get the data, but I think it is the patient experience of treatment. And I would like every single treatment.

In discussing with some of my peers, they don't feel good after dialysis. If we could get a handle on defining why they don't feel good after dialysis. And there, I have passed this measure out to many of the members on the Committee. It is kind of a make-shift idea.

But I think that that would allow the community to really understand why patients don't adhere to treatment or they have problems. Because once you don't feel good after treatment

and it repeats a few times, and you, then, start to lose hope, and it is easy to not take your medication, not go to work, not consider going to work. It also has an impact on staff and staff retention.

And I know this is a very big idea, but I think it is critical to improving the patient care on an individual basis because each treatment is individual and it is how the patient perceives it.

So, that is what I have to say.

It is so hard talking to a telephone, just to let everybody know, like this.

CO-CHAIR CROOKS: We're listening, Lori. I think that is a wonderful idea as an example of a patient-centered outcome. It sounds simple. It sounds important. I would love to see somebody work with that.

Alan?

MEMBER KLIGER: Right. Well, we mentioned this request last year as well, that patient-reported outcomes and the PROMIS set of

areas for patient-reported outcomes are in development in other areas.

Just my question for us is, where are we in the development of our patient-reported outcomes or utilizing the PROMIS set of areas for measures? Are any under development? Are there any developers that are doing that now? You guys, are you guys aware of what is happening?

MR. LYZENGA: Not in this particular area that I'm aware of. I should note that we are certainly engaging in trying to advance patient-reported outcome measure development in general. And we have started an initiative that we are calling our measure incubator. We are not directly involved in measure development through that activity, but are trying to sort of perform a matchmaking service of sorts where we are bringing together people with ideas about measurement and those who have experience with measure development funding and data, so that we can really accelerate development of measures in gap areas. And patient-reported outcomes is a

major one and that there has been significant interest in. And we can carry your thoughts that there is a need for this in this particular area for patient-reported outcomes.

MEMBER KLIGER: Yeah, specifically, it might be useful to speak to the people in PROMIS, the Patient-Reported Outcomes Measurement Information System folks, who have a really good handle on the activities going on at various places in the country on that. Perhaps communication with that group might be really helpful.

MS. SAMPSEL: And I can, so David Cella, who is very involved in all the PROMIS work, he is very active with NQF. So, typically, what happens is, when he is working on something, he says like, "Hey, let's talk about this one, how we might be able to integrate." He hasn't brought it up yet. So, certainly, it is something we can follow up with him on.

MEMBER MADDUX: So, other than the patient-reported outcomes, which I agree with,

there are three categories where I think it would be useful to have some work done.

One is frailty and understanding how we begin to measure what proportion of our patients are really functionally quite frail.

The second is with the impact, the tremendous impact of cardiovascular disease on this population of patients, there aren't a lot of bridging measures between what we consider cardiology activity and nephrology activity. And I think that would be useful.

And then, the third is the delivery systems fail to achieve data exchange between providers, particularly effectively, and creating measures around the need and expectation for data exchange, clinical data exchange that is useful, not just techno stuff, would be a way to drive that process, I think, and it would be an interesting area of development.

CO-CHAIR ANDERSON: Andrew? Andrew, is your card up, too? Do you have a comment? But your card is up or your name.

Okay.

MEMBER EVANS: I was looking at diabetes, both bridging that -- we seem to forget managing that or monitoring that, and maybe some harmonization with endocrinology because that is our No. 1 reason for ESRD and increases the larger interdialytic weight gains. And we should be at least looking at that.

MEMBER KASKEL: So, last year we had brought this up at the end, about looking at preparedness for transition as a potential area to develop. It is a problem that we face, as do the internal medicine adult nephrologists. We have a lot of young adults that transition, and I'm not sure we have any standardized measures. Everyone seems to have their own platform for seeing if they are ready to do this leap from a pediatric facility to an adult facility. I think it is an area that is open for development. I am not sure we do such a good job in preparing them.

MEMBER GREENSTEIN: So, I have to put on my access hat. The area I think that there is

a tremendous gap is in terms of looking at patients who are undergoing access procedures, redo procedures. What do I mean by that? So, you have patients who are getting dialyzed through a fistula. They are going for repeat balloon angioplasties. They are going for declottings.

And there is no handle on what is truly the right way of handling this for patients. Should they not go for the repeat procedures? Is this a procedure that has failed? They should go on to something else? Nobody has a handle on that. So, I really think there is a tremendous gap in outcomes for that.

MEMBER WAGNER: I think something that perhaps should be looked at is the idea of palliative dialysis and how to permit less-than-three-times-a-week dialysis as long as it upholds patient preferences and some quality-of-life parameters without being abusive of reasonable medical care.

MEMBER KLIGER: Yes, I was going to mention that as well. But I have one other as

well.

When you come back to thinking about patient preferences, it is also, I think, important when we develop measures, to remember that not all patients are the same. And things that one patient finds valuable or important to them will be different than what the next one does.

And if we had ways of measuring patient choices and priorities in their care, I think that that would be really important and distinct from patient-reported outcomes, really an opportunity to allow each patient and their family to decide what is really important to them.

The 85-year-old woman who really only wants to come to dialysis twice and for whom a Kt/V is totally irrelevant, that priority for her should be high in our measurement set of her adequacy of treatment.

CO-CHAIR ANDERSON: And this is more from the provider side. But one of the things

that is very frustrating, in particular, with bloodstream infections is how it is measured and calculated. The DFRs do it different than the CDC and METC. And there has got to be a way to harmonize, so everybody is measuring it the same way.

And now, providers are also responsible for, if a patient is admitted to the hospital within 48 hours if they have a positive blood culture, we are responsible for that positive blood culture. But there is no way that we would be able to get that information in a timely manner.

There are also concerns because, if you end with a bloodstream infection in one week and it continues into the next, and you are still giving the antibiotics, it is counted as two separate events. So, somehow we have to come together with how we are actually measuring and reporting because everyone is doing it very differently.

CO-CHAIR CROOKS: Lori, were you about

to say something?

MEMBER HARTWELL: Well, you know, I don't know if this is -- one of the areas that has been discussed in many of the different groups recently is rehabilitation for people who are working age. And I believe that the patient experience of treatment drives quality of life, can drive rehabilitation. But it also would be a good indicator, especially with the changes in healthcare and preexisting causes. I just wanted to throw that one out there.

CO-CHAIR CROOKS: Thank you.

MEMBER WAGNER: An area that is certainly problematic, but important for patient outcomes is the first 30 days of dialysis. Obviously, because of insurance issues, Medicare coverage, that hasn't been a subject of much attention, but, clearly, mortality and morbidity is significant during this first 30 days.

MEMBER KLEINPETER: One additional comment. We're having an influx of more undocumented individuals, and those patients are

often getting care either through the emergency department on a PRN basis -- so at least some minimal standards in terms of the care of these patients in nontraditional outpatient situations.

MEMBER WAGNER: Well, I mean, that just reminded me I don't know if this is in our mandate, but now that AKI patients will be appearing in ESRD facilities again, this, I guess, invites discussion regarding how those metrics that we typically apply to dialysis care should be applied to those populations.

CO-CHAIR CROOKS: I would like to sort of underline the mention of palliative care. I think it is really important to look at our population both coming on dialysis and the population of patients that probably are not going to benefit from starting dialysis, and whose responsibility is that? How that is measured I don't know, but to have an appropriate program in place to avoid dialyzing patients that shouldn't start.

And then, conversely, patients who are

on dialysis who are ready to call it quits, how effective are we at identifying those patients and providing the service and the transition of care so they can safely stop dialysis and go into a hospice program?

MEMBER LATTS: One more quick one, and this might be either self-serving or self-flagellating since I chair the Cost of Resource Use Committee, and I don't know if it would go here or there. But I think it would be valuable to have a resource use on dialysis measure.

CO-CHAIR CROOKS: Does that exhaust all of our possibilities for now? I know there are many more possibilities.

MR. LYZENGA: Thank you all. That is very helpful.

CO-CHAIR CROOKS: Thank you.

So, before we go to public comment, we are going to have Alexandra, I guess, go over next steps and Committee timeline.

MS. OGUNGBEMI: Yes. So, after our lovely meeting this evening finishes, we will be

optionally having a post-meeting webinar? Okay, we are not having a post-meeting webinar. So, I will send a cancellation to you for that.

The NQF staff will draft the report, and it will be posted for NQF member and public comment from August 5th to September 6th. So, that is a 30-day public comment period.

You all will have a conference call in September, on the 23rd, to review and respond to those comments. After that, the draft report will be posted for NQF member vote from October 5th to 19th, and then, it will go to CSAC for review and approval on December 9th or 10th. The Board will, then, review it on December 8th, and we will go through appeals December 12th through January 10th.

MEMBER PAVLINAC: Sorry. So, no call this Friday, is that correct?

MS. OGUNGBEMI: No call this Friday. I will send a cancellation.

MEMBER PAVLINAC: Yay, I get vacation. Thank you very much.

(Laughter.)

MR. LYZENGA: Operator, could you open the lines for public comment?

OPERATOR: Yes, sir.

At this time, if you would like to make a comment, please press *, then the No. 1.

(Pause.)

No, no public comments at this time.

MR. LYZENGA: Thank you.

Any public comments in the room?

(No response.)

No? No.

CO-CHAIR CROOKS: Okay. Well, that concludes our business for today. I thank you all for coming, for your efficient processing of this difficult, sometimes challenging work. And we will next be in touch in September, but watch your emails.

All right. Okay. Thank you very much.

CO-CHAIR ANDERSON: Thanks, everyone.

(Whereupon, the above-entitled matter went off the record at 3:59 p.m.)

D

F

M

N

W

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Renal Measures Standing Committee

Before: NQF

Date: 06-28-16

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter